UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO	MDL 2327
WAVE 4 CASES TVT and TVT-EXACT	JOSEPH R. GOODWIN US DISTRICT JUDGE

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March 12, 2017

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CONFIDENTIAL

Deposition of HARVEY A. WINKLER, M.D., held at Butler Snow LLP, 1700 Broadway, New York, commencing at 8:49 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

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TRANSCRIPT INDEX

EXHIBITS WITH ORIGINAL TRANSCRIPT

- - -

- - -

E X H I B I T S

- - -

NO.	DESCRIPTION	PAGE
Winkler 1	Amended Notice to Take Deposition of Harvey Winkler, M.D., dated March 9, 2017	10
Winkler 2	Expert Report of Harvey Winkler, M.D. Regarding TVT and TVT Exact, dated February 5, 2017	10
Winkler 3	Curriculum Vitae of Harvey Winkler, M.D.	11
Winkler 4	Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4	11
Winkler 21	E-mail chain ending August 15, 2001, Bates No. ETH.MESH.25126573 through ETH.MESH.25126575	96

- - -

E X H I B I T S

- - -

NO.	DESCRIPTION	PAGE
Winkler 23	E-mail chain ending February 7, 2005, Bates No. ETH.MESH.25042561 through ETH.MESH.25042562	99
Winkler 24	Power Point presentation Eastern Region Region of the Year by Paul Parisi, April 24, 2011	102
Winkler 20	Invoice No. 1011 of Harvey Winkler, M.D., dated January 17, 2017	107
Winkler 5	Power Point slide deck of Harvey Winkler, M.D.	163
Winkler 6	Power Point slide deck of Harvey Winkler, M.D.	166
Winkler 7	Power Point slide deck of Harvey Winkler, M.D.	166
Winkler 8	Power Point slide deck of Harvey Winkler, M.D.	166

- - -

E X H I B I T S

- - -

- - -

E X H I B I T S

- - -

DEPOSITION SUPPORT INDEX

DIRECTION TO WITNESS NOT TO ANSWER

Page Line

- -none- -

REQUEST FOR PRODUCTION OF DOCUMENTS

Page Line

- -none- -

STIPULATIONS

Page Line

- -none- -

QUESTIONS MARKED

Page Line

- -none- -

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8:49 a.m.

New York, New York

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HARVEY A. WINKLER, M.D., the Witness herein, having been first duly sworn by a Notary Public in and of the State of New York, was examined and testified as follows:

EXAMINATION BY

MR. BENTLEY:

Q. Good morning, Dr. Winkler. My name is Greg Bentley. We met shortly a couple minutes ago off the record.

Do you understand that you're here today for a deposition in the Ethicon MDL?

A. Yes.

Q. We're going to start this morning with a deposition covering your TVT and TVT-Exact report.

Is that fair?

A. Fair.

Q. I'm going to hand you what's

being marked as Exhibit 1, which is notice of your deposition.

(Exhibit Winkler 1, Amended Notice to Take Deposition of Harvey Winkler, M.D., dated March 9, 2017, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Do you see that?

A. Yes.

Q. Have you seen that before today, Doctor?

A. Yes.

Q. I'm going to hand you what's being marked as Exhibit 2, which I believe is a copy of your TVT and TVT-Exact report.

(Exhibit Winkler 2, Expert Report of Harvey Winkler, M.D. Regarding TVT and TVT Exact, dated February 5, 2017, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Is that what that appear to be?

A. Yes.

Q. And I'm handing you what's being marked as Exhibit 3, which is I believe your CV that was produced with your report.

(Exhibit Winkler 3, Curriculum Vitae of Harvey Winkler, M.D., was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Is that what that appears to be?

A. Yes.

Q. And I'm going to hand you what's being marked as Exhibit 4, which I believe is a copy of your reliance materials that was provided with your report.

(Exhibit Winkler 4, Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Is that fair?

A. Yes.

Q. You provided the same CV and reliance materials for both your TVT, TVT-Exact, Prolift and Gynemesh reports; is that correct?

A. Yes.

Q. For the record, we're going to start this afternoon with your deposition that covers your prolapse reports and we'll probably enter the same deposition exhibits that we need for that, okay?

A. No problem.

Q. Doctor, have you been deposed before?

A. Yes.

Q. How many times have you been deposed before?

A. Twice, that I recall.

Q. When was the first deposition that you recall?

A. That was years ago. I don't remember the name. It was a obstetric case while I was a resident at Einstein.

Q. And what was the purpose of your deposition, do you remember?

MR. BENTLEY: That may have been a bad question. Let me rephrase it.

Q. Were you being deposed as a fact witness?

A. No.

Q. Were you a party to the litigation?

A. Yes, as a resident.

Q. Was it for a malpractice suit?

A. Yes.

Q. And what were the circumstances of that suit?

A. Goes back way far. It was an obstetric case. I guess it was a bad outcome. I was dropped from the case.

Q. Today if I ask you a bad question, please just let me know and I'll try and rephrase it. That's entirely possible, or probably more likely.

Likewise, if you answer the question, is it fair to assume that you understood the question?

A. Yes.

Q. And you understand today that

you're giving sworn testimony that would be the same full effect as if you were before a judge and a jury?
A. Yes.
Q. What was the second deposition that you had?
A. It was as a fact witness in this MDL.
Q. And when was that?
A. About two weeks ago.
Q. Was that for your treatment of one of the patients?
A. I was an explanting physician.
Q. And was that in the Ethicon MDL?
A. Yes.
Q. You say you were an explanting physician.
So you didn't implant the mesh product in that?
A. No.
Q. Was that a prolapse or a TVT product that you were explanting?
A. I don't recall which one I explanted. It was either a TVT product or

a Prolift.
Q. So, your patient had both products, both a prolapse and an incontinence product --
A. Yes.
Q. And you removed some mesh, but you don't recall which product it was?
A. Correct. It was years ago when I removed it before all this MDL stuff started.
Q. Do you remember approximately when you would have done that explant surgery?
A. I think it was 2011-ish, 2010, '11, '12. I don't remember the exact date from the chart.
Q. And where was that deposition?
A. That was in Garden City at Heidell, Pittoni, Murphy and Bach.
Q. Have you seen that patient since you did the explant surgery?
A. So, I saw her subsequently several times after. We have not seen her in a couple years in our practice.

Q. What was her indication of what complications was she having that necessitated you to do an explant surgery?
A. She had a urethrovaginal fistula.
Q. Could you describe what that means?
A. So, she had a connection or a hole going from her urethra, the urethra is the tube where the urine comes out of, into the vagina.
Q. And what complications would have manifested from that such that she would end up with you?
A. So, I don't remember what her particular complications were offhand, but she may have been losing urine. She could have had some urgency and frequency, or just some vaginal bleeding and discomfort.
Q. And you said that you saw her after the explant surgery.
How did she progress after you took some of the mesh out?
A. With regards to my repair, she

did well. The urethrovaginal fistula was healed and the majority of her urinary complaints resolved.
Q. What about with regard to her discomfort or pain?
A. Those resolved as well, to my recollection.
Q. How much mesh did you take out, if you recall?
A. I think I took out whatever I saw in the urethra at that point in time. Probably it was, I don't know, 1-by-3, 1-by-2, somewhere around there. I don't recall.
Q. Are you talking about centimeters or millimeters?
A. Centimeters.
Q. Would that have been blue mesh?
A. I don't remember the color.
Q. When you took that mesh out, would you have sent it to pathology?
A. Yes.
Q. And what tests would you have requested that pathology perform?

A. They just did a gross look-see at it. They didn't comment on the color, once again before all this MDL started, to document that.
Q. And did the gross examination have any findings that you remember?
A. No significant findings, that I recall.
Q. So, on Exhibit 2, Doctor, which is your report.
A. Okay.
Q. It appears it's 61 pages and at the end are almost 200 footnotes; is that correct?
A. Correct.
Q. And those are citations to facts you discussed in your report; is that correct?
A. Correct.
Q. But you're reliance list shows that you reviewed several more articles than that, obviously, right?
A. Correct.
Q. On page 53 it indicates that you

signed off on the report on February 5th, 2017.
Do you see that?
A. Correct.
Q. And is that accurate?
A. Yes.
Q. When did you write this report, Doctor?
A. My gosh, I spent all, like, December and January writing these reports. My wife said, "When are you coming back to visit the family?"
I spent the entire holiday weeks writing the reports, weekends, nights, days, all December and January literally.
Q. Right. And what was your -- how did you go about deciding what to write? What was your technique that you might have done this, if you can describe?
A. Well, I wanted to tell a little bit about myself and how I got to where I was and then to write about why I think the TVT product has really made a difference in many women's lives as -- for

the positive, as well as to write the scientific data that I was aware of backing those claims.
Q. Okay. And does this report include a complete list of all the opinions you intend to offer at trial?
A. I always reserve the right to add additional opinions.
Q. As you sit here today, do you have any additional opinions that you intend to offer at trial?
A. Not that I'm aware of today.
Q. And does this report contain a complete list of the bases for your opinions included within the report?
A. Yes.
Q. Do you still stand by all of your opinions in this report?
A. Yes.
Q. Are there any changes you would like to make to this report at this moment?
A. No. Unless we find a typo here and there.

Q. It's a long report.
Let's look at what I believe was marked as Exhibit 3, which is your CV.
A. Okay.
Q. Did you prepare this CV?
A. Yes.
Q. And is this a true and accurate reflection of your professional experience?
A. Yes.
Q. Did you make this CV for this case?
A. No.
Q. This is your CV you've used in your normal day-to-day professional activities?
A. Yes, and it may get updated every month, every two months, whatever. You know, whenever I do something, I try to put it in to try to keep track.
Q. You add new information as you have new items to add?
A. Correct.
Q. So your CV contains your

education, your training, your publications, things like that?
A. Correct.
Q. And do you remember the last time you updated this CV?
A. I think the last update that I did, this is it. I haven't updated it since. I'll probably do an update in about a month.
Q. Do you have something you intend to update it with?
A. Going to Australia to be a national speaker in their urogynecological annual conference.
Q. Other than that, are there any things missing or that you would like to change in your CV?
A. No, nothing missing. We've submitted other publications, so if they get accepted, I would add them.
Q. And likewise there's nothing you need to take out or that you know of that's incorrect in there?
A. Correct.

Q. Do you have multiple versions of your CV that you would use for different purposes?
A. This is pretty much the one I like -- I stand to use today. I try to send this one out.
Q. Looking at Exhibit 3 which we entered, which I believe is your reliance list, is this a complete list as you sit here today of all the reliance materials you've reviewed --
A. I have Exhibit 4.
Q. I'm sorry, 4. Thank you. That will probably happen again.
A. That's okay. As long as we're looking at the same thing.
Q. So, is this reliance list, as you sit here today, a complete and accurate list of materials you relied upon in reaching your opinions in this case?
A. Yes.
Q. Is there anything that you would like to add or take out of it today?
A. Not right now.

Q. Do you have anything you intend to supplement it with that you know of?
A. The reliance list, no. We did bring --
THE WITNESS: Should we take that picture out?
MR. ROSENBLATT: (Handing.)
MR. BENTLEY: This is what you're talking about?
THE WITNESS: Yes.
That's the one we brought, right?
MR. ROSENBLATT: Greg, there's another picture I need to get printed.
MR. BENTLEY: We can do it at a break.
BY MR. BENTLEY:
Q. Doctor, can you please describe for me a little bit about your education, where you went to school and when?
A. Sure. Sure.
Q. And if you want to review your CV.
A. No, it's just for the date.

This way I don't have to memorize the dates and whatnot. Although I know them. I did live them.
In 1988 I graduated from Yeshiva University with a BA. In 1992 I graduated from the Albert Einstein College of Medicine. I then did a residency from '92 to '96 also at the Albert Einstein College of Medicine in obstetrics and gynecology. From '96 to '98 I did a fellowship in urogynecology, what is now known as female pelvic medicine and reconstructive surgery, at Evanston Hospital in Chicago under Peter Sand. From '98 to 2002 I worked at the Maimonides Medical Center as the director of the division of urogynecology there.
Q. Where is that?
A. That's in Brooklyn, New York.
Q. Okay.
A. And then from 2002 to present day I've worked at North Shore LIJ, which is know known as Northwell Health. I'm the co-chief of division of urogynecology

Page 26

there. I'm the program director for the fellowship in female pelvic medicine and reconstructive surgery there. I'm an associate professor at the Hofstra Northwell School of Medicine.

Q. What courses do you teach?

A. So, I don't teach any courses in the medical school. I teach residents in the hospital, medical students as well as the fellowship program. I manage and direct that.

Q. The medical school students that you teach, is that just general medical, or have they specialized at that point?

A. Excuse me?

Q. What do you teach the medical school students?

A. So, medical students, generally I would teach them surgical principles. I would have the most -- they don't come to our office, but they come to the operating rooms with us and give them the first introduction to surgical principles, risks and benefits of surgeries that we perform.

Page 27

Q. Is that specific to urogynecological surgeries, or is that just general surgical principles?

A. Well, they're general surgical principles in urogynecologic surgery, but we would then discuss specific to urogynecology.

Q. And likewise you're seeing fellows or students in the fellowship program, what emphasis are you -- what surgical knowledge or what emphasis are you teaching them?

A. Well, there's certain basic knowledge that I teach them always about surgical principles. We treat the whole body, not just the pelvis, but we do specialize on the pelvis or complications that can occur or pathology that can occur with female pelvic disorders.

Q. And what female pelvic disorders do you treat?

A. So, I treat the main two that we treat are urinary incontinence and pelvic organ prolapse. However, we'll also treat

Page 28

bladder pain syndromes. We'll treat complications after pregnancy, vaginal complications. We'll treat recurrent urinary tract infections. We'll treat symptoms of vaginal atrophy. Some of us will deal with sexual dysfunction, although I don't deal very much with sexual dysfunction, and we also will deal with complications regarding the bladder and/or vagina from surgery, so surgical postoperative surgical complications that can occur.

Q. You said "some of us will treat sexual dysfunction."

How many other doctors are in your group?

A. So, we have in the immediate practice where I practice we have two other physicians, two other attendings. We have three nurse practitioners and we also have the fellows. We have another -- Northwell has another practice out east with another doctor that we also work with with the fellowship program, but there's

Page 29

no intermingling of patients from those other practices.

Q. When you treat stress urinary incontinence or incontinence generally, what are the treatment options that you would normally go through for any particular patient?

A. So, for stress urinary incontinence, after our history and physical examination, we have a discussion about what -- I explain to them what the problem is and what the situation is, and we'd also have a discussion about treatment options.

First and foremost, every patient is told that she can do nothing, this is not a life-and-death situation; it's a quality-of-life situation. So she can do nothing. Obviously they're there for a reason. They're not there to do nothing, but they do get all told that.

Then we will talk about behavioral modification and/or Kegel exercises associated with it. We'll talk

Page 30

about intravaginal devices or occlusive devices, pessaries, vaginal inserts that are options. We'll talk about off-label use of medications. We'll also then talk about surgical options. We'll talk about midurethral slings.

Q. I'm sorry to interrupt you.

When you're talking about surgical options, you're starting to delineate what the options are in that category?

A. Correct.

Q. So, the first one you said was midurethral slings?

A. Midurethral slings.

Q. What other surgical options do you have?

A. We have Burch procedures and autologous pubovaginal slings and periurethral bulking.

Q. When you were in medical school and your fellowship, what incontinence procedures were available that you were trained on?

Page 31

A. So, in my fellowship I was trained on Kelly-Keenedy plications, anterior repairs, which nobody really does today. For stress urinary incontinence procedures, that was my primary teaching in residency. In fellowship my primary education was in Burch procedures and pubovaginal slings and we did periurethral bulking back then too.

Q. And your fellowship was 1996 to 1998?

A. Correct.

Q. Then subsequently to your fellowship, the midurethral slings came to market and you learned how to implant those, correct?

A. Correct.

Q. And how did you learn to implant midurethral slings like the TVT?

A. So, I was familiar already with placing in pubovaginal slings. I went to Philadelphia to talk and observe Dr. Vincent Lucente, who had learned the procedure, and after that I performed the

Page 32

procedures.

Q. And who is Dr. Vincent Lucente?

A. He was one of the preceptors for Gynecare in 1999 when I learned how to do the procedure.

Q. Do you have an understanding of whether Dr. Vincent Lucente works for Ethicon or worked for Ethicon?

MR. ROSENBLATT: Object to form.

Q. You can answer.

A. He was a consultant. He wasn't a employee of Ethicon.

Q. He was getting paid by Ethicon.

A. I know.

Q. Can you describe for me what a pubovaginal sling is made of?

A. So, there are different types of pubovaginal slings. There's autologous pubovaginal slings which is where we harvest or take a piece of tissue from the patient that we're operating on. So it's their own tissues.

Q. And what part of the body do you harvest that from?

Page 33

A. Fascia lata which is a strip of fascia from the thigh.

Then there are slings that you can use from other humans, cadaveric slings, so there was cadaveric tissue slings that you can use, autografts. And then there's something, xenografts which are tissues from other animals.

Q. And what animals would you harvest from using -- or what --

A. I get the question.

Q. Let me just get the question out.

What products are sold that are xenografted?

A. So, some products have been on the market and then have left. There was porcine dermis that was on the market.

Q. Is that Pelvicol?

A. Yes, Pelvicol.

Today you would use there's bovine fetal pericardium, which is something called Xenform, that you can go ahead and use.

Page 34

Q. Who makes Xenform?
A. Xenform, I don't know who makes it, but Boston Scientific is the company that you would buy it from, but another companies harvests it.
Q. Sometimes those are referred to as biologics?
A. Correct.
Q. And do you use biologics today?
A. I've used biologics in the past. I haven't used biologics in the past several years for vaginal surgeries.
Q. Did you have bad results with biologics?
A. Biologics have not been shown to really give you good long-term efficacy for slings.
Q. Are you talking about the literature or in your personal experience?
A. In the literature.
Q. So in your personal experience, you had good results with biologics?
A. I would say my experience was consistent with the literature.

Page 35

Q. So we went through the pubovaginal slings, Burch.
You still do Burch today?
A. I still do Burch procedures. I offer Burch procedures. I don't do as many as I used to in the past, but it's a procedure that I am entirely comfortable with performing.
Q. Are there different types of Burch procedure?
A. I do the Tanagho modification of the Burch procedure and then there are different ways that people -- not different ways, but different sutures that people may use for the Burch procedure. I prefer a 2-0 Gore-Tex suture and I put two sutures on each side. The Burch procedure really works with scarring. So you want to try to increase the scarring that occurs in the retropubic space. So I also put little pieces of gel foam underneath the suture bridges to try to increase the scarring that takes place in order to give longevity to the procedure.

Page 36

Q. How many patients do you treat on average a week or a month, if you have an estimate?
A. I see approximately, me personally and not the nurse practitioners who see patients, I probably see about 50 to 60 patients a week.
Q. And how many surgical procedures do you estimate you do in a week?
A. A week, I don't know. I do something -- at this point, I think I do somewhere around 200, 225, somewhere around the 200.
Q. Per year?
A. Per year, yeah. 225, somewhere in there.
Q. And approximately how many procedures do you think you're performing a year for incontinence, or to treat incontinence?
A. The majority of my patients I'm treating with incontinence one way or the other. 175, 200. 175-ish.
Q. I'm just trying to get an idea.

Page 37

A. Yeah, you know, listen, I haven't looked at these numbers in a long time.
Q. Do you treat men and women?
A. No, just women.
Q. Of the 175 women that you do surgery on per year for incontinence, approximately how many of those would you estimate are Burch procedure?
A. Zero to 1.
Q. So, the majority -- what procedure are you performing on the 175 women to treat incontinence?
A. Midurethral slings.
Q. And what kind of slings are you using?
A. So, I use retropubic slings. I use transobturator slings, as well as the mini sling.
Q. Which retropubic sling are you using today?
A. So, I use TVT-Exact as well as the Boston Scientific Advantage.
Q. You don't currently use the

TVT-R, the classic TVT Retropubic?
A. No.
Q. Then you said you're also using the Boston Scientific Advantage?
A. Mm-hm.
Q. One of the other things is we need to have audible answers so Marie can get the transcript down.
A. Was I not talking loud enough?
Q. You said "mm-hm."
So one of the retropubic slings you're using today was the Boston Scientific Advantage, correct?
A. Correct.
Q. And you have both of those slings available for you in your operating room for you to choose from?
A. Correct.
Q. And how do you decide with any given patient if you want to use the TVT-Exact or the Boston Scientific Advantage?
A. To be honest with you, I think they're very similar.

One of the things that we're required to notify our patients of, because of this MDL, is the recent allegations against Boston Scientific that it's a counterfeit mesh. So if a patient doesn't want a Boston Scientific mesh, then I can use a TVT-Exact.
Q. So your initial recommendation is going to be Boston Scientific Advantage, but you're going to present to them that there's been some issues potentially with the mesh and if they are concerned about that, then you go to TVT-Exact? Is that a fair statement?
MR. ROSENBLATT: Objection to form.
A. No.
Q. Let's start with how do you decide between TVT-Exact or Boston Scientific Advantage if you're going to recommend the retropubic sling for patients with incontinence?
A. So, if I'm doing it together with another prolapse surgery, I prefer to

stick with one company at this point in time, use the same meshes. So if I'm doing, let's say, a sacrocolpopexy or anything like that, then I would go ahead and use the Boston Scientific mesh. I don't have a personal preference over one or the other. I think they're both excellent slings and function pretty much the same way and pretty much placed in the same way.
Q. So you have no preference one way or the other of which sling you're using?
A. I don't think one is better than the other, absolutely not.
Q. What percentage of your women that you treat for incontinence do you think you use the retropubic sling?
A. Thirty percent.
Q. So, since slings have been available, have you changed the product that you use? Or, which products --
MR. BENTLEY: Let me strike that.

Q. Which TVT retropubic slings have you used throughout your career?
A. So, the majority of them have been TVT and Boston Scientific.
Q. Okay.
A. I have passed the AMS sling retropubically. They have the SPARC when it came out I guess 15 years ago and then they had a modification where they had a bottom-up. So I've used AMS or Astora's slings. I've also used maybe once or twice a Caldera sling retropubically.
Q. And you said you've used some biologics.
Are retropubic slings available in biologic mesh?
A. There's tissue that's available in biologics that you can go ahead and use. I don't know if they have a specific indication for pubovaginal slings in terms of biologics, but once again, I said I don't really use biologics for my slings because of the efficacy.
Q. So we talked about approximately

Page 42

30 percent of the women you treat for incontinence and that you use slings for a year, about 30 percent of those are retropubic.

Approximately how many of the 175 sling procedures that you're doing are obturator?

A. Today, so things have shifted a little, but today probably another 30 to 40 percent are transobturator. Probably about, you know, 40 percent.

Q. And what are the advantages with an --

A. Forty-five, somewhere around there.

Q. Maybe a little bit more than your retropubic?

A. Maybe slightly more, yes.

Q. What are some of the advantages of having an obturator-based approached versus the retropubic?

A. So, the obturator approach has a little less voiding dysfunction and lower incidence of bladder perforation, not

Page 43

zero, but lower incidence, and it also takes away the risk of bowel perforation. Those are the main ones.

Q. Do you tell your patients the risks and benefits of retropubic versus obturator approaches?

A. Absolutely.

Q. Because ultimately it's the patient's decision on whether she wants to undergo this procedure and take the risk to get the benefits, right?

A. I agree with you a hundred percent.

And each of my patients gets literature on the procedures. They get information on their stress incontinence, and they ultimately decide whether or not they want to go to the operating room to undergo this procedure.

Q. And which obturator slings are you using?

A. Today mostly Boston Scientific Obtryx.

Q. Is there a reason you don't use

Page 44

the Ethicon obturator sling?

A. I've always liked the outside-in procedure of placing the transobturator sling. I never had a problem with the meshes. And as you heard me say before, I think they're very, very similar. It's just in terms of the way I was taught and the way in my hands and I think it's a little easier to teach as well, so I use the transobturator sling outside-in.

Q. We've talked about a couple of different retropubic slings and obturator slings, and those are all polypropylene-based slings, right?

A. Correct.

Q. But as we've already discussed, there's some advantages to the design of some of the slings versus other slings; is that correct?

A. Correct.

Q. Have you ever used any of the Ethicon obturator slings?

A. No, not that I recall.

Q. And then the third type of sling

Page 45

that you're using is the mini sling; is that correct?

A. Correct.

Q. And which mini sling are you using?

A. Boston Scientific Solyx.

Q. So that would be approximately another 30 to 40 percent, is that fair?

A. I think it's probably closer to about 20 percent right now. I've recently been using slightly more of the mini slings as data has come out regarding their efficacy.

Q. And what would be the advantage to using a mini sling?

MR. ROSENBLATT: Object to form.

Q. You can answer.

A. As compared to the transobturator sling, I think an advantage is the decreased possibility of developing groin pain.

Q. Have you, in your experience using mini slings, have you noticed any advantages to using the mini sling versus

Page 46

the other slings we've discussed?
A. Besides the groin pain, no.
Q. The groin pain is associated with mini sling -- let me just clean this up.
Doctor, you said that you're using approximately 25 to 30 percent mini slings today; is that correct?
A. Something like that, yeah.
Q. In your experience using those slings, have you used any --
MR. ROSENBLATT: Object to form.
I think he said 20 percent. I just wanted to make that clear.
MR. BENTLEY: Okay.
A. Twenty percent.
Q. Doctor, in your experience using mini slings today, have you noticed any benefit to using those slings versus the obturator or retropubic slings we already discussed?
A. So, I would use the mini sling in place of patients who in the past I would have put a transobturator sling in.

Page 47

The data is consistent out there right now with mini slings as compared to transobturator slings. It would be unusual for me to replace a retropubic sling with a mini sling for the patients that I use retropubic slings on.
Q. That wasn't really my question.
My question is you're using a mini sling today, correct?
A. Correct.
Q. And in your experience using the mini sling, have you noticed any advantages to using that sling versus a full-length sling?
A. I wouldn't use the mini sling in the same patient I use the full-length sling in.
Q. So you have no reason to use a -- why are you using a mini sling then?
A. Okay. So, my mini sling patients, more commonly I'm putting them in patients who have occult stress incontinence. These are patients who do not have complaints of stress

Page 48

incontinence, but I'm doing a prolapse repair on them and then as part of our evaluation for the prolapse repair, we've identified that there's a good possibility that these patients are going to leak postoperatively from stress incontinence. So I'm using the mini sling in the majority of my patients, not all, majority of patients who would have occult stress incontinence.
Q. So you are implanting a sling in women prophylactically during a prolapse procedure with the anticipation that she may develop incontinence later?
A. No, that's not correct. That's not prophylactic. A prophylactic procedure is in a patient who would not leak with reduction of her prolapse.
So these patients have stress incontinence. It's just being masked by their prolapse.
So, I am not a fan of putting in prophylactic slings.
Q. That would be inappropriate?

Page 49

MR. ROSENBLATT: Object to form.
BY MR. BENTLEY:
Q. Do you have an opinion on whether or not it would be inappropriate to put a sling in during a prolapse procedure if the woman wasn't currently suffering from incontinence?
A. Well, there's a risk for them developing urinary incontinence after the procedure. So I think it's inappropriate.
I think this is a discussion that you need to have with your patient of whether or not the patient wants to take on the risks of the additional surgery. Any time you do surgery there are risks. So you have a discussion with the patient if they want to take on the risks of the procedure for the 25 or 30 percent chance that they may lose urine after the surgery and whether or not it would be symptomatic.
Q. Do you recommend putting a sling in prophylactically during prolapse if she's not currently suffering from

Page 50

incontinence?
A. I never recommend putting in any of these products. It's ultimately the patient's decision deciding whether or not they want to undergo the procedure.
Q. And going back to the retropubic.
You said that, I believe you said you use Boston Scientific Advantage if you're also doing the abdominal sacrocolpopexy; is that correct?
A. Correct.
Q. And if you're not doing the abdominal sacrocolpopexy or ASC, are there other situations where you would use the Boston Scientific Advantage retropubic sling?
A. So, I can use the TVT or the Boston Scientific Advantage if I'm just putting in a sling. It doesn't really matter. It depends on -- I don't have a preference for one over the other.
Q. What percent of the women where you're putting a retropubic sling in are

Page 51

you also doing a ASC repair, if you have an estimate?
A. I do about six to eight ASC repairs a month. I would say 90 to 95 get a sling, 90 percent.
Q. So, 90, 95 percent of your ASC repairs also get a sling?
A. Yeah.
Q. And so those would be the women that would also get the Boston Scientific Advantage because you want to use the same company's product?
A. Yeah, they would either get an Advantage, an Obtryx or a Mini Sling.
Truthfully, the largest player in the space right now and supporting the space is Boston Scientific.
Q. The third category of slings we were discussing called mini slings, do you have an understanding of why they're called mini slings?
A. They're shorter-length slings than the traditional full-length slings.
Q. What's the length of the Boston

Page 52

Scientific Solyx that you put in?
A. I think it's 9 centimeters.
Q. And do you know what the length of the full-length slings are?
A. Well, so, out of the box, I don't recall. Maybe it's 24.
Don't quote me on that.
Q. Right.
A. But we cut the slings. So depending on how big the patient is will depend on how much sling gets implanted.
Q. When the sling's implanted, when the retropubic sling's implanted, what's the general length it's implanted in the woman's body?
MR. ROSENBLATT: Object to form.
Q. From your experience.
A. Probably, if I'd have to guess, somewhere around 18 centimeters.
No one's ever asked me that question before.
Q. Do you have an idea how much mesh you're trimming off, on average usually that's left over?

Page 53

A. (Indicating.)
Q. About six centimeters, is that consistent with your --
A. We're taking off, I guess, about six on each side.
Q. Is it fair to say that generally you think the mini sling has half as much mesh as the --
MR. BENTLEY: Strike that.
Q. Is it fair to say you think the length of the retropubic full-length sling is about twice as long as the mini sling?
A. Yeah, we can say that.
Q. Do you have an understanding of why companies would introduce slings that are smaller or mini?
MR. ROSENBLATT: Object to form.
A. I think they wanted to reduce the incidence of the groin pain or some of the complications that were occurring with the full-length slings.
Q. You said, I think, the mini sling that you use is an obturator-based approach?

Page 54

A. Yeah, they're all -- yeah, it's an obturator-based approach. That's what I use it interchangeably for the implanting is slightly different than an obturator approach because I would do the outside-in for the obturator and the mini sort of is inside going into the obturator muscle.
Q. So you're using a mini version of the Ethicon TVT-O which is inside-out?
MR. ROSENBLATT: Object to form.
A. I think I need to explain the procedure a little.
Q. Let me give you a question.
So, the Boston Scientific Obtryx is an outside-in, right?
A. Yes.
Q. And then the mini sling that you're using is an obturator-based approach, correct?
A. Theoretically, yeah.
Q. But it's inside-out?
A. Inside-out, yeah.
Q. Are there mini slings available

Page 55

in the retropubic passage?
A. Not right now, no.
Q. Are there previously?
A. I think TVT Secur was a little more going in the same path as the retropubic sling which would placed, but I really didn't use that product.
Q. What that --
A. TVT Secur.
Q. You did use it or you didn't use it?
A. I didn't use a TVT Secur.
Q. You never did a TVT Secur?
A. I may have done one, but it was not a product that I used.
Q. Let's go back.
You trained on TVT Retropubic, the classic TVT from Dr. Lucente, correct?
A. Correct.
Q. Who did you train under with TVT Obturator, or did you?
A. Yeah, I did. I went to a cadaver lab and that was an AMS-sponsored cadaver lab.

Page 56

Q. Did you do any cadaver labs or training for the Ethicon TVT-O?
A. No, not that I recall.
Q. Did you do the -- a cadaver lab or training for TVT Secur?
A. Not that I recall.
Q. And did you do a cadaver lab or any training for TVT-Exact?
A. No, not that I recall.
Q. Do you know if there's any differences in the TVT-Exact as compared to the TVT classic Retropubic?
A. Yes, I know that there are differences.
Q. What are the differences?
A. So, the needles are thinner, the trocars to place the sling in, the -- there's a plastic sheathe that goes over the TVT-Exact. So you have different ways of implanting the sheathe. TVT-Exact is laser-cut, the mesh that I use, and the traditional TVT that I had used was mechanically-cut.
Q. Did you use laser-cut TVT-R?

Page 57

A. Not that I recall.
Q. You said there's sheathes with TVT-Exact; is that correct?
A. Yes.
Q. Do you remember if there are sheathes with TVT Retropubic?
A. There's no sheathe that goes on a TVT Retropubic. It's sort of the needle that screws into the device that you would -- the TVT device that you would use to implant the polypropylene and pass the trocars.
Q. Do you have an understanding of why having a sheathe with the TVT-Exact is helpful?
A. I think it's an easy way to pass the sling. I've read in other reports that people liked the TVT-Exact because now they can do one cystoscopy.
To be honest with you, I've always done one cystoscopy. I just left the trocar in from the traditional retropubic and unscrewed it, went into the other side and passed both in my slings.

Page 58

It passes very nicely and very easily. It does not require a tremendous amount of force to put the sling in. It's a nice delivery device.
Q. When you say it's easy to pass, are you talking about the -- can you describe what you mean?
A. So, the force that I would need in order to perforate through tissues.
Q. So it minimizes maybe the friction of the implanting device against the tissue?
A. You can say that, yes.
Q. And conversely, without the sheathe, maybe there would be more friction and more force required to implant the device?
A. So, I never tried with or without the sheathe with the needle because there was no reason to go ahead and do that. But it is a thinner needle than the classic. So it required less force and passed nicely and, in my mind, maybe there was less chance of

Page 59

perforation.
Q. Do you know what the diameter of the Exact trocars are?
A. With -- I know there's a difference with or without the sheathe. Somewhere around the 3 millimeter range, but I don't have that committed to memory.
Q. Do you know what the diameter of the TVT Retropubic classic was?
A. Once again, not committed to memory, but I think around 5 millimeters.
Q. Do you have an understanding of any clinical implications from having a thinner trocar for the patient?
A. I have not seen any clinical implications of one versus the other that one's better.
Q. If there was some study showing a difference, would you want to see those?
A. I'm always willing to look at studies, yes.
Q. If there was studies that showed decreased morbidity with a thinner needle, would that be useful information for you?

Page 60

MR. ROSENBLATT: Object to form.
A. Studies are -- all studies are useful information to me, whether they're good or bad, showing pluses or -- positives or negatives.
Q. If there are studies showing decreased morbidity with a thinner needle, would that guide your selection of which device to use?
A. So, if there's one needle that has decreased morbidity and it's a safer needle, quote/unquote, sure, I would like to use the one that's safer.
Q. When did you start using TVT-Exact, if you remember?
A. I don't remember. I apologize.
Q. Was there a break where you stopped using TVT Retropubic and switched to TVT-Exact that you remember?
A. So, I think that the Boston Scientific Advantage sling came out before the TVT-Exact. So, I did, I think, if I recall correctly, that you would use the Boston Scientific Advantage slings, and

Page 61

then when TVT-Exact came out, once again I said I think they're interchangeable at this point in time.
Q. The first polypropylene sling that you trained on was a TVT, correct?
A. Correct.
Q. And then when would you have trained on the Boston Scientific Advantage?
A. We're going back many years here. I wish I could remember for you.
Q. Was there a -- did you use the TVT Retropubic exclusively for a while?
A. Yes.
Q. And then at some point you trained on Boston Scientific Advantage?
A. So, no.
So, first came the Transobturator Monarch, right.
Q. The AMS Monarch?
A. Yes.
Q. Let's go through the procession of your history using slings.
Initially you used TVT

Retropubic, correct?
A. Correct.
Q. You trained under Lucente in '98?
A. Correct.
Q. And then do you have a memory or recollection of what sling you used next?
A. So, I always continued to use the retropubic. It's not that I shifted over one to the other. But then the transobturator sling came out and I also learned that technique and offered those slings to my patients as well.
Q. So you went Ethicon TVT Retropubic and then AMS Monarch.
Transobturator approach was available and then you added that to your surgical options to treat incontinence, correct?
A. Correct.
Q. And then what came after that?
A. So then after that, I think the Boston Scientific Advantage sling came out. So I did transition some of my

retropubics over to the Boston Scientific Advantage.
Q. And part of the reason for that was because you wanted to -- if you were using the Boston Scientific prolapse kit, you also wanted to use the Boston Scientific incontinence product; is that correct?
A. Yes. And also if I was using anything for prolapse, because I would do transvaginal mesh procedures also, but if I was using -- I tried to stick with the same company, and I also liked the smaller, thinner needles.
Q. And which product had the smaller, thinner needles?
A. So, the Boston Scientific Advantage.
Q. Do you have an understanding --
A. You know what, let me clarify. You're probably right.
There's an Advantage Fit and there's an Advantage.
Q. And one of the advantages of the

Advantage was smaller needles?
A. The Advantage Fit had a smaller needle. I use it interchangeably because they also had a thicker needle and that was the regular Advantage.
Q. Doctor, do you treat complications that could arise from sling procedures?
A. Yes.
Q. Do you treat complications that arise from prolapse procedures?
A. Yes.
Q. Are you referred women who have had a mesh implanted from some other doctor?
A. Sometimes.
Q. And they're referred to you to treat complications from some other product that's been implanted that you did not implant; is that correct?
A. Correct.
Q. And similarly, you have an understanding that sometimes you might implant a product in a female patient and

she might seek treatment from another doctor, for whatever reason, for a complication, correct?
A. Correct.
Q. So it's hard to say what the experiences of all of your patients that you've implanted products in; is that correct?
MR. ROSENBLATT: Object to form.
A. Correct.
However, I will tell you, and I mean, it's a small community in the urogyn field. I've been in the New York area for a long time, and I've actually asked some of my colleagues have they seen any of my complications and we do vice versa. As strange as it might seem, and I know all doctors say this, the majority of patients I know don't come back, but generally if there was a real significant complication, I think that I would hear about it.
Q. Would you consider yourself a high-volume mesh implanter?
A. It depends what you consider

Page 66

high volume, but I probably do more of these procedures than a lot of people around in the New York area.
Q. And that probably affects your complication rate probably.
The high volume helps you do it safer; is that fair?
MR. ROSENBLATT: Object to form.
MR. BENTLEY: Let me rephrase it a little bit.
Q. Would you agree that you as a high-volume or having more frequent opportunity to implant these mesh devices gives you enable ability to implant them safer and have a reduced complication rate; is that fair?
A. I think my complication rate is lower than what is quoted in the literature.
However, generally when I consent my patients, I use the complication rate that's available in the literature.
Q. And we'll get to the literature

Page 67

in a little bit.
Would you agree that the literature shows that more high-volume implanters have a lower rate of complications? Is that fair?
A. Yeah, there's some data to show that more experienced, quote/unquote, surgeons may have a lower complication rate.
Q. How many women do you think you treat a year for complications that arise from a sling that was implanted to treat incontinence?
A. From a sling specifically?
Q. Yes.
A. Five to ten.
Q. And how many women do you think you treat a year that have complications that might have arisen from a prolapse treatment that used a polypropylene mesh?
MR. ROSENBLATT: Object to form.
A. Repeat the question.
Q. Sure. Well, we talked about you think you do five to ten -- you think you

Page 68

see about five to ten women a year to treat them for complications that arose from a polypropylene sling for incontinence; is that correct?
A. Well, so, let's clarify what we mean by a complication, because if voiding dysfunction is a complication, I'm seeing more of those. If we're talking other complications, more significant ones, that's what I'm talking about the five to ten.
Q. Let's go broad first.
Overall for all complications, how many women do you think you see a year that have complications that came from a sling, a polypropylene sling that was implanted to treat incontinence?
A. Overall probably about, I don't know, 15, 20, some of them, including my patients.
Q. And approximately five to ten of those might have what you said I think is serious complications?
A. Complications that may require

Page 69

more treatment than, let's say, a medication or something like that.
Q. And what would the serious complications include?
A. So, the serious complications that I would commonly see, the most common is mesh exposure.
Q. And what else?
A. Sometimes patients will have some pain with intercourse associated with the implant. Some patients can have fistulas or mesh erosion into the bladder or the urethra.
Q. The treatment can involve surgery; is that correct?
A. Correct.
Q. And sometimes not surgery?
A. Correct.
Q. And sometimes multiple surgery, correct?
A. With a sling, you usually can get it on the first surgical procedure.
Q. Okay. You also see women that have suffered complications after having a

Page 70

mesh product implanted to treat prolapse, correct?
A. Yes.
Q. And approximately how many women do you think you see on average per year that are suffering from complications from a prolapse treatment that involved a mesh?
A. About another -- about -- with mesh, probably about five a year.
MR. ROSENBLATT: Greg, I will give you a little leeway, but just try to separate the prolapse questions for the afternoon depo.
MR. BENTLEY: Okay.
BY MR. BENTLEY:
Q. We said approximately there's five to ten serious complications women per year per sling and approximately five prolapse.
Is there another group that you're seeing that have complications that had both a prolapse and an incontinence? Is that like a separate group?
A. No, that's probably all included

Page 71

in there.
Q. So you're probably doing approximately 10 to 15 revision surgeries per year or --
A. No.
Q. How many revision surgeries do you think you're doing per year?
A. Five, six revision surgeries a year.
Q. And those revision surgeries are usually for a mesh exposure?
A. Exposure or erosion into bladder, urethra.
Q. Are you ever removing, going in and removing the mesh, not just the exposed mesh?
A. So, it depends on what the problem was. I'll give you a for instance, if you'd like.
In a patient who had a erosion into the bladder from a Prolift mesh, which is going to be later on in the afternoon, I will take out a wider dissection.

Page 72

We can save that for later, if you want.
Q. Of your five to six on average revision surgeries per year, how many of those do you think you're going in and excising more mesh than just what's exposed?
A. Well, I always take out a little more mesh than is exposed in order to get fresh edges so I don't have tension on my repair. It really depends on why I'm going in to take the mesh out. I will say rarely do I feel if it's a prolapse mesh do I need to take the entire mesh out.
And for slings, if it's the sling is working and it's a simple little exposure, then I would just try to keep the sling intact and remove the small piece that is exposed in order to get a fresh edge to close it out.
Q. Some of the women that have had a sling, they might have urinary retention; is that correct?
A. That's correct.

Page 73

Q. And to surgically fix that, you just go in and cut the mesh, correct?
A. Correct.
Q. It's called a release procedure sometimes?
A. Yeah. So it's an incision into the sling to release the sling.
Q. And no mesh --
A. I had to do one on a urologist's wife once.
Q. And no mesh is actually removed in that procedure?
A. I don't remove mesh in that procedure.
Q. When you're trimming or removing mesh that's exposed, do you always send that to a pathologist?
A. I always send it to my path department. Generally they would just do a gross on it.
However, there have been cases where we've had to then send the mesh off to plaintiff attorneys' path departments and I happen to leave that to the path

Page 74

department.
Q. And for fairness, it also gets examined by the defense pathologists. Do you know that?
A. Yes, I know that.
Q. Doctor, have you ever done any work as an expert in litigation before this case or these reports?
A. I've done some malpractice work, but not -- this is my first product liability type of work.
Q. And did you submit expert reports in those other cases?
A. No. I've also actually way back when, I did some work for -- no reports, but I did review some charts for Caldera.
Q. Have you ever examined a patient for what's called like a medical exam for litigation purposes?
A. Yes.
Q. When did you do that?
A. I think they've been mostly for malpractice cases in the area when I was

Page 75

an expert on them. I am not sure if I -- I have not done any examinations for any patients, that I'm aware of, that I remember, for this particular MDL.
Q. But you've done some examinations for med-mal cases; is that correct?
A. Correct.
Q. Did you do those examinations on behalf of the defendants or the plaintiffs?
A. Defendants.
Q. Have you ever done any work on behalf of plaintiffs?
A. So, I've worked on charts and reviewed charts for the plaintiffs. However, I never have gone to testify for plaintiffs.
Q. Do you have any estimate of how often you do work for plaintiffs versus defendants?
A. In the past, I did some more. Probably right now it's down to about five percent. There's only one or two people

Page 76

that call me at this point in time.
Q. So 95 percent of the work you do for litigation is for defendants?
A. Correct.
Q. Has your practice changed in that you see more patients now or less patients throughout your career? Or, can you describe that for me?
A. So, as I've been getting older, I think the practice has changed a little, and I'm seeing more surgical patients as time goes on. That's about it. Surgery seems to be getting busier.
Q. You were initially trained on the Burch, but today you don't really perform it very frequently; is that correct?
A. Correct.
Q. When do you think you, if you remember, when did you stop doing Burch probably?
A. Probably somewhere in the late 2000s.
Q. Okay.

Page 77

A. I had a progression. I mean, so, the last patients that I did Burch on were as part of the cure study where in that case, they did recommend a prophylactic procedure in patients who were getting open abdominal sacrocolpopexies, those were Burch patients. As I transitioned away from open to robotic, we stopped doing the Burch procedure.
Q. You still do the robotic procedures today, correct?
A. I do the robotic procedure. So, we transitioned away from doing them open abdominal sacrocolpopexy, and I transitioned to more a more minimally invasive technique with laparoscopic robotic.
Q. And that's for prolapse repair?
A. That's for prolapse repair.
Q. Doctor, have you ever done any work consulting for a medical device manufacturer?
A. Yes.

Q. Which companies have you worked on behalf of?
A. I'll try to remember them. Most of them are in the CV.
Q. If you want to look at your CV, that's fine.
A. I've worked with Boston Scientific on developing products. I have worked with Caldera, AMS.
Q. What page are you on?
A. Now I'm reading off memory, to be honest with you.
Q. Got you.
A. In terms of devices, I have consulted with Kimberly-Clark in terms of an over-the-counter device for stress incontinence.
I have -- I'm trying to think if there's anything else.
Q. You're talking about consulting for product design?
A. So product design, yes, I consulted with Boston Scientific on product design, as well as Caldera, and as

well as probably with AMS Astora.
Q. And then another -- I notice on your CV it says you've taught or precepted on behalf of AMS, correct?
A. Correct.
Q. And you've also taught on behalf of Boston Scientific?
A. Correct.
Q. Have you talked on behalf of any other companies?
MR. BENTLEY: I'm sorry, that was a horrible question.
Q. Have you taught on behalf of any other medical device manufacturers?
A. In terms of cadaver labs, no. These are the two that I recall that I've done, the two companies.
Q. Other than cadaver labs, have you taught on behalf of any other medical device manufacturer?
A. So, I was a preceptor for J&J in the early 2000s.
Q. For what product?
A. For TVT. And I also -- I don't

know if I ever -- I may have and I may not have precepted for Caldera. That I don't really remember if anyone came to the OR for that or not, to be honest with you.
Q. For Caldera?
A. Yeah. And I precepted for Boston Scientific as well.
Q. If you could look at page 6 of your CV, which is marked as 3.
A. Yes.
Q. There's a listing of your teaching experience; is that correct?
A. Yes.
Q. And this has, for example in August 2003 you did an AMS monarch cadaver lab where you were lecturing an instructor.
Do you see that?
A. Yes.
Q. And then there's an AMS below that, then a Boston Scientific.
Does this reflect your teaching on behalf of medical device companies?
A. Yes.

Q. And you testified that you taught on behalf of J&J in the early 2000s; is that correct?
A. Yeah, but I don't think I ever did a, like, a cadaver lab or anything like that for them. At least not that I recall. Some of this I'd have to put together and think back.
Q. So this is only teaching experience specific to cadaver labs; is that your testimony?
A. Yes.
Q. Why are these other entries on here that don't say "cadaver lab"?
A. Which one?
Q. For example, April 2008 female urology and urogynecology symposium lecture, that's not a cadaver lab, is it?
A. No. So where it says, like, October 2003 AMS Monarch cadaver lab. Usually when I did a cadaver lab, I tried to write it down.
Q. Is there any reason why you don't include your other teaching

Page 82

employment on here from J&J?
A. No. This is for the medical school. So they want to know what I'm treating and teaching, you know, in big groups. They're not really interested in a doctor coming and watching and seeing me.
Q. When you say that you precepted for J&J in the early 2000s, approximately how many years did you teach on behalf of J&J for?
A. I don't think it was very long, and I don't think it was a lot of docs. It may have been for probably two, three years only.
Q. Did you get paid?
A. Yes.
Q. Are there other teaching activities you've done on behalf of medical device manufacturers that are not included on here in addition to the J&J work?
A. For cadaver labs, I tried to write them down. If I was invited to a

Page 83

meeting or an advisory, I may have missed that early on in my career, because to be honest with you, I just didn't record all that stuff back then.
Q. But ultimately you started including that information on your resume?
A. Correct.
Q. And where are those non-cadaver lab stuff that later in your career you started including on here?
A. So, if I did an advisory board, that would be on here.
Let's see what page that's on.
So, starting on page 2 Other Professional Positions. I wrote that I was a consultant for AMS. And once again, it may have been earlier, but this form for the medical school came out around, I guess, somewhere several years ago when I was up for associate professor, so five years ago or somewhere. So that's when I started really recording. Some of them I have to go back to memory. But right now that's what I have and that's what's

Page 84

recent.
Q. So if you were going to update this today, would you add being a consultant for Ethicon or J&J to your CV?
A. I guess I would add it, yes, at this point in time. It's mostly for precepting. Once again, I didn't do any -- I didn't do any cadaver labs or whatnot, but I could add that, yes.
Q. So it's your testimony today that the only work you've done for J&J other than this expert work in the MDL is for preceptorship?
A. So, I did that and I may have gone to some meetings that they have sponsored and I may have gotten paid for that. I don't recall what they were.
Q. So you may have spoken on behalf of --
MR. ROSENBLATT: I just want to object to form. You're asking him about the past 20 years or so.
MR. BENTLEY: Right.

Page 85

BY MR. BENTLEY:
Q. Your CV doesn't reflect any employment for J&J whatsoever, does it?
A. It doesn't -- I was never employed by J&J.
Q. You got paid by J&J, didn't you?
A. Correct.
Q. And your CV doesn't reflect any of those payments or any of that work, correct?
A. Yes. It's not because I'm trying to hide anything like that. Once again, it's going back a long time. I totally forgot about the stuff that I did for J&J when I put this together. I didn't include any of the other stuff that I got paid for back then from Boston Scientific or from AMS. Once again, it wasn't an academic thing, so I didn't put it on my academic CV.
Today we have -- there's more disclosure going on. I fill out all my conflict of interests and it's disclosed on there, and you can go on the Web site

Page 86

for Medicare and see it as well.
Q. I mean, you would agree that conflict disclosure is important information, wouldn't you?
A. I agree that's important, and I usually adhere to the requirements of the time.
Q. So, in addition to the J&J work that you did in the early 2000s, there's also Boston Scientific and AMS work that's not on this resume?
A. There may be. But once again, some of the cadaver labs are on the CV. So work that I did for them is there.
If I did any consulting on device development or on any kind of improvements to any of their devices that I would have consulted on, I probably didn't include that on here on this one.
Q. You didn't include on here on this one, you're talking about this CV?
A. On my CV, I probably would not have included the early 2000 stuff.
Once again, academically, it

Page 87

really wasn't pertinent at that point in time, so I didn't include it.
Q. That was in the early 2000s?
A. Correct.
Q. At what point would you have changed and decided that information would be pertinent to include on your CV?
A. So, when I started doing this and really updating this on an ongoing basis when I was up for associate professor, that's probably what I started.
And let's see when I was up for an associate. So, I was approved for an associate professor in 2013. I probably started working on this format of this CV about a year earlier in 2012.
Q. So, you did some teaching on behalf of, according to your CV, you did some teaching on behalf of Boston Scientific and AMS.
Additionally, did you do some other work for those companies?
A. Yeah. I would consult with them on device development. I would consult

Page 88

with them if they were bringing in -- out a new product, they would show it to me. I would maybe do a cadaver lab with them. I would give my advice on new product development as well as products that they have in development.
Q. And that information is not listed on your CV?
A. Well, it is. Consultant. I started putting, in 2012, I started writing down when I was a consultant and recording that kind of stuff.
Q. So that information just isn't recorded prior to 2012; is that fair?
A. Yes.
Q. And additionally, you did some, it looks like, studies with some of these companies; is that correct?
A. Correct.
Q. It says "Contracts, grants and sponsor research" on page 9.
Do you see that?
A. Okay.
Q. And is this a list of the

Page 89

studies you worked on?
A. Yes. Not all the studies. I got some clarification on what studies they really wanted on here, but these were some of the major studies and anything that would have a possibility with a grant or grant money that was obtained, but we do a lot of studies where in the office where we don't get money for or we don't get grants for and those generally aren't included in here unless it's a large multicenter study.
Q. And the grant money doesn't go to you; it goes to your hospital, right?
A. Does not go to me.
Q. But you included on here studies that received grant money that went to your hospital; is that fair?
A. Yes.
Q. Is this a complete list of the work you've done or the studies you've done that received grant money to your hospital?
A. That I'm aware of, yes.

Q. Are there studies that you might have forgotten about or didn't include?
A. Yes, there's always that possibility. Once again, I started doing this format around 2012. So before that, some of that may have been from memory and just having to go back to some of the open payroll, whatever accounts there were in the hospital to find out from them if they were -- if grant money was obtained.
Q. So you went back to see if grant money was obtained, you included those studies on your CV? Is that it?
A. I tried to, yes.
Q. And looking at your studies, it looks like in 2003 you started a study with the AMS Monarch. Do you see that? You were an investigator?
A. Which one?
Q. The second.
A. On page 9?
Q. Yes.
A. Yes.
Q. So that's a study that you did

of the AMS Monarch that was from 2003 to 2005 $29,000 disclosed, correct?
A. Correct.
Q. So at least in -- some time in the early 2000s, you were including studies on here that you received money for, correct?
A. Correct.
Q. Then two down from there there's another AMS study that you participated in?
Do you see that?
A. Yes.
Q. And that one was started in 2005 and ended in 2008; is that correct?
A. Yes. So once again, this is going back eight years. I'm going to assume if I didn't put money down is we probably didn't enroll patients in or the study changed or something like that.
Q. But if you enrolled patients, you would have included on here?
A. I likely would have.
Once again, this is going back a

long time. I don't really remember and if we enrolled a patient or not.
Q. I'm having a hard time.
How do we know what you worked on in the 2000s? Is there just no way to know at this point?
A. Whatever's here is what I remember at this point in time. Whatever I thought was pertinent to in order to for academically, that's why I put it on there. And there may have been a patient or two in the perigee one, I just don't recall.
Q. Then on the next page the complete entry on the top is 2006-2008.
Do you see that's a Boston Scientific study you worked on?
A. Yes.
Q. And then I guess --
A. See, I started to get better.
Q. You get better at what?
A. I started to get better at recording the stuff and remembering it because it was just available to me.

Q. What was available to you?
A. No, the information to put down.
Q. But the information was available to you in the early 2000s also, wasn't it?
A. Yes, but I didn't put this CV together then.
Q. You didn't keep a CV from the beginning of your career?
A. I did. Once again, not putting down everything like I needed to put down in this CV.
Q. And it's your testimony that you started making a complete CV around 2013 when you were up for assistant professorship?
MR. ROSENBLATT: Object to form, characterization.
A. So, I always had a CV.
When I needed to put this form together, there was more information that was requested than I probably had on my old one, and that's why I needed to do some going back. Like I didn't keep a

Page 94

record of every single grand rounds that I did. I was doing a lot back then. I had to go back and try to figure out which ones I gave, where they were and whatnot.
Q. Today would you like to go back and update this CV and add some work for any companies?
A. I mean, I can add the consultant for J&J. Once again, that was in the early 2000s. I don't think academically they would care at that point in time going back, but sure, I'd put it down. It's not a problem.
Q. Today you'd like to do that?
MR. ROSENBLATT: Object to form. You don't have to do anything.
BY MR. BENTLEY:
Q. I'm not asking you what you have to do.
If you had the opportunity to update this CV, would you like to add --
A. I probably wouldn't formally update it at this point in time. I would just leave it at this for the academic

Page 95

stuff 'cause once again, that was 14 years ago. If somebody wanted to know it, I have no problem with disclosing it.
Q. What was 14 years ago?
A. When I did the consulting work for J&J.
Q. And today it's 2017.
Fourteen years ago would have been?
A. 2003, '4. So 13, 14 years ago.
Q. And your testimony today is that's when your consulting with Ethicon stopped?
A. That's what I recall. I don't remember, once again. I don't have the 1099s from back then. I don't have information from back then or any tax information.
MR. BENTLEY: Take a break?
MR. ROSENBLATT: Sure.
(Recess taken from 10:06 a.m. to 10:21 a.m.)
BY MR. BENTLEY:
Q. Doctor, we're back from the

Page 96

short break.
Are you ready to go?
A. Yes.
Q. Before the break, we were discussing that you may have worked as a preceptor for Ethicon in the early 2000s.
Do you remember that?
A. I didn't say "may." I did work as a preceptor for them.
MR. BENTLEY: I'm going to hand you what's being marked as Exhibit 21.
(Exhibit 21, e-mail chain ending August 15, 2001, Bates No. ETH.MESH.25126573 through ETH.MESH.25126575, was marked for identification, as of this date.)
THE WITNESS: I just want to comment that on the grants, we discussed this beforehand, but none of this grant money went to me. It all went to my hospital.
MR. BENTLEY: Appreciate that, thank you.

Page 97

BY MR. BENTLEY:
Q. So, Exhibit 21 is a e-mail, Bates on the bottom right which we refer to to identify pages, it's ETH.MESH.25126573.
Do you see that?
A. Yes.
Q. And this is an e-mail from Greg Slusser on August 2001.
Do you see that?
A. Okay.
Q. And do you know who Greg Slusser is?
A. I mean, he works for Ethicon. I can see that.
Do I remember him? I don't --
Q. It was a while ago.
A. Yeah.
Q. And you see the subject line of the e-mail is "Preceptor summit information"?
A. Correct.
Q. Then it's an e-mail string, you can see further down is the earlier

Page 98

message and the original e-mail from Brian Luscombe on August 14th, 2001.
Do you see that?
A. Yes.
Q. And he starts the e-mail: "Attached is the information recently mailed to all preceptors with regard to the TVT preceptor summit meeting."
Do you see that?
A. Yes.
Q. Then on the next page on Bates the last three is '574, do you see there's a list of people that have confirmed their attendance?
A. Yes.
Q. And your name, Harvey Winkler, is at the bottom of that first list.
Do you see that?
A. Yes, it is.
Q. And that's consistent with your testimony today that in the early 2000s, you were preceptor for J&J or Ethicon, correct?
A. Yes.

Page 99

Q. Then I'm going to hand you what's being marked as Exhibit 23.
(Exhibit Winkler 23, e-mail chain ending February 7, 2005, Bates No. ETH.MESH.25042561 through ETH.MESH.25042562, was marked for identification, as of this date.)
BY MR. BENTLEY:
Q. This is another e-mail that was produced to us by Ethicon, and its Bates is 25042561.
Do you see that?
A. Yes.
Q. And this is an e-mail from February 7th, 2005 from Donna Abely.
Do you see that?
A. Mm-hm.
Q. And she starts: "Thanks, Jim. Dr. Hall is working on gathering all of this information. She just called to me inform, however, that because Dr. Winkler, the speaker, is traveling from the east coast he's requesting a two-day honorarium."

Page 100

Do you see that?
A. Yes, I do.
Q. And this is in 2005 you're speaking on behalf of Ethicon, a J&J subsidiary, correct?
A. I don't know if I would call it speaking on behalf of them. If I remember correctly, this was a lecture on the pelvic floor incontinence and this was about using mesh on the pelvic floor.
Q. And you were being paid, correct?
A. I was being paid, yes.
Q. Then I'm going to hand you what's being marked as exhibit --
A. And I think this is on my CV, by the way.
Q. Could you point me to what page of Exhibit 3 it lists that you worked on behalf of J&J and you spoke --
A. It's page 7 of my CV, Cedars-Sinai Medical Center.
Q. On page 7 of Exhibit 3, which is your CV, you spoke at Cedars-Sinai Medical

Page 101

Center; is that correct?
A. That's what this was, correct.
Q. And it says "guest lecture," correct?
A. Yes.
Q. And nowhere on your CV does it say you got paid by Ethicon, correct?
A. There's nowhere on this CV that you need to write who your honorarium came from.
MR. BENTLEY: I'm going to move to strike.
MR. ROSENBLATT: Greg, let him answer the question. Then you can move to strike.
Q. Finish the answer, please.
A. It's not required to put on your CV where the honorarium comes from.
Q. Do you remember what my question was, Doctor?
A. No.
Q. Nowhere on this CV does it state that you were paid by Ethicon to speak at Cedars-Sinai, does it?

Page 102

MR. ROSENBLATT: And you can answer the question and provide the context that you think is necessary.
A. Once again, I wasn't paid to speak there. They invited me. It was an honorarium to compensate me for my out of time out of the office.
Q. My question is very precise, and then if you need to explain afterward, that's totally fine.
But my question is nowhere on your CV does it say that you got paid to speak at Cedars-Sinai by Ethicon, as we just saw in that e-mail, does it?
MR. ROSENBLATT: Object to form; asked and answered.
A. It does not say that on my CV.
Q. Doctor, I'm going to hand you what's been marked as Exhibit 24.
(Exhibit Winkler 24, Power Point presentation Eastern Region Region of the Year by Paul Parisi, April 24, 2011, was marked for identification, as of this date.)

Page 103

BY MR. BENTLEY:
Q. This is a Power Point titled: "Eastern Region Region of the Year," dated April 24, 2011.
Do you see that?
A. Yes.
Q. And then on the bottom left corner it says: "Professional education."
Do you see that?
A. Yes, I do.
Q. If you turn the page it says: "Keys to winning," on the second page.
Do you see that?
A. Yes.
Q. In the bottom right corner it says "KOLs."
Do you know what KOLs are?
A. Key opinion leader, yes.
Q. Were you a key opinion leader for Ethicon?
MR. ROSENBLATT: Object to form.
Q. If you know.
A. I'm a key opinion leader today.
I did not know if I was a key

Page 104

opinion leader back in 2005, or who considered me what.
Q. But today you consider yourself a key opinion leader for Ethicon?
MR. ROSENBLATT: Object to form.
A. I consider myself knowledgeable in the field. Am I -- if you want to consider me a key opinion leader, yes, some people may, some people may not.
Q. If you turn the page on page 4 of this Power Point, there's a little 4 on the bottom left.
Do you see?
A. Mm-hm.
Q. Yes?
A. Yes, I do. I'm sorry.
Q. That's okay.
Then on the bottom right -- well, on the top left it says "KOL."
Do you see that top heading?
A. Yes.
Q. Then on the bottom right it says "Metro," and your name is listed under "Metro."

Page 105

Do you see that?
A. Yes, I do.
Q. So 2011, at least according to this Power Point, you're considered a key opinion leader for professional education for Ethicon.
Is that fair?
A. Yes.
Q. Today as we sit here and seeing these documents, would you like to add some of this information to your CV?
A. I don't think that this is pertinent to my CV.
If somebody asks me to disclose any of this information, I have no problem with disclosing it.
Q. So you wouldn't want to add any of this information to your CV?
MR. ROSENBLATT: Objection.
A. I don't know if I would add it or not to my CV. Once again, being a consultant, I can put on. That's not a problem. Whether or not it's going to make a difference for academic promotion,

Page 106

I don't think it will and that's why I maintain the bulk of my CV.

But I don't think I was a consultant for Ethicon in 2011. I may have been considered a key opinion leader, but I don't recall being a consultant for them in that year.

You probably have access to that information easier than I do.

Q. Just so I understand, for purposes, for academic purposes, you don't feel that you need to update your CV? Is that your testimony?

MR. ROSENBLATT: Object to form; mischaracterization.

A. I didn't say that. I said I would think about it, if adding them as a consultant to the CV.

Once again, I'm not going to do it when I go back right away, but I don't have a problem adding that to my CV and disclosing that to anybody.

Q. If you end up testifying at trial before the jury, would you want to

Page 107

update your CV before beginning the trial to include this work for Ethicon?

MR. ROSENBLATT: Object to form.

Which consulting work are you referring to?

BY MR. BENTLEY:

Q. You can answer the question, if you understand.

A. So, I would consider adding my consulting work that I did for J&J in the early 2000s. Thank you for reminding me.

Q. Appreciate it.

Doctor, I just handed you an exhibit, which is I believe your invoice from the TVT report.

What number did I put on that bottom right?

A. 20.

(Exhibit Winkler 20, Invoice No. 1011 of Harvey Winkler, M.D., dated January 17, 2017, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. And does this Exhibit 20 reflect

Page 108

the work that you've billed on -- does this Exhibit 20 reflect the work that you've billed to prepare your TVT report?

A. Yes.

Q. And the description of your work includes review of articles, research and writing report; is that correct?

A. Correct.

Q. And is this all the time that you put into those activities, reviewing, researching and writing your report?

A. I put some more activities in together, but I've been so busy, I have not had a time to add any of that stuff up yet.

Q. So as we sit here today, you have more time that needs to be billed that you know of?

MR. ROSENBLATT: Object to form.

You're asking about what went into his report, right?

MR. BENTLEY: Right. Thank you.

BY MR. BENTLEY:

Q. Do you have any additional time

Page 109

to bill for the preparation of your report that you know of today?

A. I may have, yes.

Once again, I don't know the hours or the numbers 'cause I had sent this report in January 17th. Today is March -- what is today, March 12?

Q. Right.

A. I signed off on this report on February 5th. So I probably did more work in between.

Q. In between?

A. In between January --

Q. 17?

A. Well, this is up to January 3rd, right.

Q. I got you.

A. I just sent out the bill on the 17th before I went away.

So, there may well be more time that I have spent on, and likely there is.

Q. Do you have an estimate of how much more time after January 3rd you're going to bill for --

A. I don't recall. I apologize.
MR. ROSENBLATT: And Greg, I'm happy to produce the information when we get it.
THE WITNESS: Yeah, not a problem.
BY MR. BENTLEY:
Q. Your hourly rate for preparing report and reviewing material was $650 an hour, correct?
A. Correct.
It's expensive to live in New York.
Q. That's true.
Is that also your rate for this deposition today?
A. So, my deposition -- I didn't really discuss this, to be honest with you. I thought this was going to be a seven-hour deposition, and then you guys increased it to a nine-hour deposition.
So, yes, it's either -- it will be around the 650 an hour. My deposition daily rate is 7,000. I was going to

figure out what we were going to bill for today.
Q. Charge him more.
A. I don't know about charge him more. I wouldn't charge more than the 650 an hour, but we will be here for 12 hour -- how long are you going to keep me here?
Q. We'll see.
Is your daily rate for trial the same?
A. It's 8,000. It's in my CV.
Trials don't go past nine o'clock at night, right?
Q. No comment.
So, let's look at your report.
A. Okay. The TVT report, to be exact?
Q. TVT report we've entered as Exhibit 2, I believe.
A. Okay, I'm ready.
Q. If you could turn to page 7 of your report, please.
THE WITNESS: Could we go off the record for a second?

(Discussion held off the record.)
BY MR. BENTLEY:
Q. Earlier we were discussing your use of different polypropylene slings.
Do you remember that?
A. Yes.
Q. And you testified that you used TVT classic.
A. Okay.
Q. I believe you said you used the machine-cut TVT classic; is that correct?
A. Yes.
Q. And then today you use TVT-Exact, correct?
A. Correct.
Q. And TVT Exact is laser-cut, correct?
A. Correct.
Q. I thought you said you never used a laser-cut TVT-R; is that correct?
A. I don't think that I have.
Q. And so on page 7, that last paragraph, the third line down you say: "I have implanted traditional TVT

mechanically-cut and laser-cut."
Do you see that?
A. Yes.
Okay. So, what I mean to clarify -- so, doesn't matter if you call it -- I call TVT classic or mechanically-cut, laser-cut. Traditional cut meant general TVT, not traditional mechanical-cut. So I've done both.
Do you understand?
Q. I don't.
So, before you switched to TVT-Exact, you were using TVT-R or TVT classic, correct?
A. Correct.
Q. And you testified today that you used mechanically-cut TVT-R, correct?
A. Correct.
Q. Which you no longer use today, correct?
A. Correct.
Q. But your report says you used TVT, mechanically-cut and laser-cut.
That's what that says, right?

Page 114

A. It does.
Q. Can you explain that?
A. I mean, what we're calling traditional, classic, I just meant traditional TVT as TVT-type slings and then I separate it into I've done mechanically-cut TVT slings and laser-cut TVT slings.
Q. Just so I understand, the laser-cut retropubic device made by Ethicon that you use is TVT Exact?
A. Correct.
Q. And did you use TVT Retropubic laser-cut?
A. Not that I recall.
Q. Okay. Doctor, on page 7 you have some estimates of how many procedures you've done.
Do you see that?
A. Yes.
Q. How did you come to those numbers?
A. These are very gross estimates. I don't have case logs and whatnot. So

Page 115

these are just trying to think back of how many I do a year and how much I did in fellowship.
It's very, very gross.
Q. You didn't go back and review any operative reports or anything like that?
A. No, no.
Q. Do you have an estimate of how many of the 3,000 midurethral slings you've implanted, how many of those women had complications?
A. It depends what you consider a complication.
Q. Let's start broad.
Just any complication, do you have an estimate of how many of the 3,000 slings you've implanted the woman had a complication?
A. I don't have my own estimate. I would go with pretty much what's in the literature, to be honest with you.
Q. My question is more in your experience and estimate, taking the

Page 116

literature apart, or aside, in your estimation, do you have any idea of how many of the 3,000 slings you've implanted that those women had any type of complication?
A. Any type of complication, if we're talking about exposure, erosion, going back I would say somewhere between, I don't know, two, three percent.
Really this is gross 'cause once again I have not gone back.
Q. I'm not asking you to guess.
A. Yeah, it's a guess.
Q. And then likewise, you don't have an estimate of how many of those 3,000 slings you implanted, you don't have a reasonable or accurate estimate of how many had an erosion, correct?
MR. ROSENBLATT: Object to form.
MR. BENTLEY: Let me rephrase it.
BY MR. BENTLEY:
Q. Do you have any reliable way of calculating what percent of your 3,000

Page 117

slings you implanted, how many of those women had an erosion?
A. From the 3,000, absolutely not. I don't have a reliable way.
Q. And do you have a reliable way of estimating how many of the women, of the 3,000 women you implanted slings, how many of those women developed dyspareunia?
A. I don't have that number available to me.
Q. Do you have any reliable way of estimating how many of the women that you implanted slings in, your 3,000 women that you implanted slings in, how many of those women developed chronic pain?
A. I don't have that number. However, I do believe that number is low.
Q. If you could turn your attention, please, to page 8 of your report. At the top you say: "I have had extensive experience in treating complications after gynecologic surgeries."
Do you see that?

Page 118

A. Yes.
Q. (Continuing) "Including after Burch, needles procedures, autologous and midurethral sling procedures."
Do you see that?
A. Yes, I do.
Q. Do you have any reliable estimate or method for estimating how many complications you've treated after a midurethral sling procedure?
A. A number? I don't know. If I treated maybe a hundred or 50 to -- maybe 50, 75.
I don't really remember those numbers.
Q. In preparing this report, did you undertake any investigation into how many women you have treated for complications from midurethral sling procedures?
A. I didn't do a review of my studies of that, no.
Q. Do you have that information available for you to review if you wanted

Page 119

to?
A. Not easily available, no.
Q. The next paragraph on page 8, you state that you received further training in preventing, identifying and treating surgical complications during residency.
Do you see that?
A. Yes.
Q. Your residency was before the midurethral slings were available, correct?
A. Correct.
Q. So you couldn't have received training on how to treat midurethral slings, could you have?
A. Well, all slings have the same complications except for synthetic slings which may have complication -- which do have a complication of erosion or exposure. And we can debate whether or not autologous or biologic slings have that risk or not.
MR. BENTLEY: Let me re-ask it.

Page 120

BY MR. BENTLEY:
Q. During your medical residency, did you receive training on how to treat specifically complications of midurethral slings made out of polypropylene?
A. Yes, because those slings have the same risks, except for erosion and/or exposure, as do the autologous slings, as do some Burch complications, and as do general complications of surgical procedures.
Q. What training did you receive on how to treat complications from polypropylene slings during your residency?
A. During my residency, I did not receive any training in polypropylene slings.
I did receive training during my fellowship in synthetic slings in treating Gore-Tex slings that we had placed for synthetics.
Q. What slings were available that were made out of Gore-Tex?

Page 121

A. So, you would cut a sheet of Gore-Tex at that point in time and use that as your implantable.
In the late -- in the 1990s, there was no specific indication for any of the meshes that people were using at that point in time, whether it was Marlex, Mersilene, Gore-Tex. People were cutting their own pieces and using them as the sling.
Q. There was no sling product manufactured that was made of Gore-Tex; is that correct?
A. Gore-Tex never made a sling, that is correct.
Q. Do you have an opinion as to whether the Gore-Tex slings were safe and effective?
A. I think the Gore-Tex slings had a high complication rate.
Q. Do you have any understanding of why they had a high complication rate?
A. They're a microporous mesh and the sling would get encapsulated as

Page 122

opposed to integration into the tissue, and that would have been one of the reasons why they had a high complication rate.

Q. So, I think I understand. Your testimony is that the Gore-Tex slings had a high complication rate because they were microporous, in part?

A. Yes.

Q. And the slings, the size of their pores is an aspect of the design of the mesh; is that correct?

A. Correct.

Q. And the geometry of the mesh is part of the design of the product, correct?

A. What do you mean by "geometry," that it's linear?

Q. The mesh is a knitted product that's they take a monofilament polypropylene and knit it into a mesh, correct?

A. Correct.

Page 123

Q. And it creates a certain pattern or a pore structure, correct?

A. Correct.

Q. And there's large pores and smaller pores and different pores, correct?

A. Correct.

Q. And I believe it's your testimony that the Gore-Tex slings had a pore complication that fell apart because they were microporous?

A. Correct.

Q. Which is the geometry of the mesh or the knitting design, correct?

A. Correct.

Q. Okay. Do you have an opinion as to whether or not it was the Gore-Tex material inherently causing the complication, or was it the geometry of the Gore-Tex pores that was causing the complications?

A. I don't have an opinion on either.

Q. But today there's no Gore-Tex

Page 124

slings available, correct?

A. Not that I'm aware of, correct.

Q. And you're not implanting Gore-Tex slings today, right?

A. No.

Q. Doctor, you learned the Burch procedure during your residency, correct?

A. I was exposed to it in residency. I really learned it in fellowship.

Q. Thank you. And you used it as a frequent treatment for incontinence early on in your career, correct?

A. Yes, it was a primary procedure for incontinence.

Q. Did you have good results with the Burch? Doing that procedure, did you have good results?

A. Yes.

Q. And by "good results," you had good efficacy rates?

A. Yes.

Q. And low complication rates?

Page 125

A. Depends what you consider low. There were complications associated with the Burch procedure, but it's a good procedure.

Q. At least in your hands, it was a good procedure and safe and effective; is that fair?

A. Yes.

Q. Do you have any estimate as to what your complication rate would have been when you were doing the Burch procedure to treat women with incontinence?

A. Once again, somewhere in the -- depends on what you consider a complication, if a wound infection is a complication. So I think overall, I don't have a -- that's really far back going remembering, but if we're taking all complications, wound infections, pain, you know, could have been six to eight percent.

Q. Would you consider that low?

A. Depends on what you're

Page 126

considering a complication, again, and what is a major complication, what's a minor complication.

The most common complication from all these anti-incontinence procedures is actually a urinary tract infection. Many people don't consider that a complication.

So it depends on what you consider low and high.

Q. Recurrent UTIs could be a more serious complication; is that fair?

A. Recurrent UTIs could be more bothersome than just one UTI, for sure.

Q. When you meet with women today that are suffering from incontinence, you discuss the various treatments, as we discussed earlier, correct?

A. Mm-hm.

Q. Yes?

A. Yes.

I'm sorry. Once again I apologize. My fault.

Q. And you discuss non-surgical and

Page 127

surgical interventions, correct?

A. Correct.

Q. And when you discuss surgical interventions, you discuss the midurethral slings, correct?

A. Correct.

Q. And do you still discuss the Burch procedure as one of the options today?

A. I mention it to them. Every single -- I try to give every single patient the IUGA handout, the International Urogynecological Association handout on stress incontinence on the patient's first visit. So in there it's described all the options. So if the patience doesn't remember what the options are, they can take it home and read it. I encourage them to go to the Web site. I encourage them to do their own research on the options, as well as the products themselves.

Q. And when you discuss the Burch procedure today with your patients as a

Page 128

potential option for treating the incontinence, what do you generally tell them is your complication rate with the Burch procedure?

A. So, I would tell them it's not a commonly performed procedure today that I do, as the midurethral sling has sort of become the standard in treatment for stress incontinence, which has been ratified or promoted or agreed upon by the major societies in the U.S. and internationally. I tell them my complication rate is low with the Burch procedure. However, the overall morbidity with abdominal incision, recovery is longer associated with the Burch procedure, and the data does not show that the Burch procedure has a better overall success rate than the midurethral slings.

Q. So, you want to give patients complete knowledge so they can make a full and informed decision; is that fair?

A. Yes, I do.

Q. And when you discuss potential

Page 129

treatment options for incontinence, you give them the option of Burch; is that correct?

A. It's in there, yes.

Q. And what do you tell your patients about the complication rate? Do you only classify it as low, or do you give them an estimated complication rate?

A. So, that's a really hard question to answer about what the complication rate is and even the percentages are available even amongst the studies that you're going to look at. I will tell them it is low. The likelihood of them having major complication, death is a major complication, the likelihood of that happening is low, but I try not to quantify exactly what low and rare is, and we try to come to an understanding with the patient in order to figure out what's going to be the most appropriate treatment that they would like to go forward with.

Q. Do you give your patients a range of what you anticipate the

Page 130

complication rate would be for Burch?
A. They don't ask that.
Q. So you don't tell them?
A. I don't give them a range of what the complication rate will be.
Q. And similarly, do you give your patients an estimate of what you think the efficacy would be for Burch?
A. I say they're comparable. And I usually would say somewhere around 80 to 85 percent success rate for a midurethral sling, so you can extrapolate that. It's probably around the same for a Burch procedure.
Q. You haven't undergone any type of statistical analysis to figure out what the true complication rate is for Burch, have you?
A. Myself, I have not done that. I go by the literature and the systemic reviews and the Level I evidence.
Q. And in preparing this report, you didn't do a statistical analysis of what you think the true rate is of

Page 131

complications of Burch?
A. I personally did not perform a systemic analysis.
I did my own Pub Med searches.
Q. You don't have SAS on your computer at home, do you?
A. No.
Q. And similarly, you didn't do a statistical analysis of what you think the true complication rate is of polypropylene slings, correct?
A. I did not do a -- my own systemic review. I read the Level I evidence, and I'm aware of the Level I evidence that I've been reading throughout my entire career.
Q. What is the definition of Level I evidence?
A. So, Level I evidence is meta-analysis and systemic reviews. After that would be randomized control trials.
So, I try to stick with Level I and Level II evidence if it's available.
Q. Is there a difference between

Page 132

systemic reviews and systematic reviews, or is it just kind of synonymous?
A. I use them interchangeably.
Q. We talked about you have experience treating complications, including after Burch procedures; is that correct?
A. Yes.
Q. How often do you see patients that have had a complication from Burch?
A. We don't see it commonly and it's rare because there aren't that many Burch procedures being done anymore.
Q. Did you used to see more patients that had complications from Burch?
A. Yes.
Q. And what would the complications that you --
MR. BENTLEY: Let me rephrase that.
Q. The women that you saw that had complications from Burch back when Burch was done more commonly, what were the

Page 133

complications that you saw and treated?
A. So, complications could be urinary retention, voiding dysfunction, suture erosion, hematoma developing from the incision, pain with the incision, infection with the incision.
THE WITNESS: Can you read back what I told him already?
(The requested portion of the record was read by the Court Reporter.)
A. And prolapse occurring after the Burch procedure.
Q. And what surgical interventions did you have to perform to treat complications that might have arisen from Burch?
A. So, it depends on what the complication was. Sometimes there were sinus tracts that developed abdominally to the suture that we put in. So we would need to go back in abdominally and remove that permanent suture. Sometimes the patient would develop urinary retention or significant voiding dysfunction, where we

Page 134

would need to go in vaginally and do a urethrolysis. Those are the more common procedures we were doing.

If someone had a prolapse failure afterwards and wanted treatment for that, we would go in and treat their prolapse.

Q. What kind of sutures were you using to do your Burch procedures?

A. 2-0 Gore-Tex sutures is what I used and what I would still use today.

Q. Doctor, when we talk about mesh erosion, sometimes I see "exposure" and "extrusion."

Do you have some definition that differentiates those three words, or are they kind of interchangeable?

A. So, what I like to use in my documentation if I'm writing the note, I prefer to use the word "exposure" when there's mesh visible in the vagina. I prefer to use "erosion" when mesh has migrated into a visceral organ, specifically most commonly here would be

Page 135

either in urethra or into bladder. Although mesh, and depending on what type of meshes we're talking about, they can migrate to other places.

Q. And you don't use "extrusion" in your practice?

A. Not commonly. It's not a common term that I use.

Q. On page 4 of your report, there's a paragraph that starts -- I'm sorry, on page 35 of your report there's a paragraph that starts: "The surgical risks".

Do you see that?

A. Yep.

Q. About halfway down you say: "Although if necessary, surgical correction for exposure is a relatively simple procedure performed on an outpatient basis."

Do you see that?

A. Yes, I do.

Q. Sometimes it's not relatively simple to fix the exposure; isn't that

Page 136

correct?

A. An exposure from a TVT or any type of midurethral sling, as a general rule, is not that difficult a procedure to perform. It's right there in front of you. It's a vaginal procedure and you don't -- it's not a terribly difficult procedure.

Q. Is it all --

A. And you know what, you don't have to perform it all the time. If it's not bothering the patient, you can leave it.

Q. But if it's symptomatic, you need to do some sort of intervention, correct?

A. Correct.

Q. And is it always performed on an outpatient basis?

A. Not always. Sometimes I will try to, and I'll discuss with the patient of what they would rather me do, but sometimes in the office we can try to, if it's just a little piece of an edge

Page 137

eroding through, that we can try cutting that little piece off in the office and giving some vagina estrogen. It doesn't always have to be.

Q. Okay. And using your definition that you just gave me, now I understand.

Your next sentence you say: "Erosion of mesh into the bladder area is rare."

Is the surgical intervention to fix an erosion more invasive than the surgical intervention to fix an exposure?

A. I don't know if I want to use the term "invasive."

I can use the term "a little more complicated."

Q. And by "complicated," there's going to be more dissection, correct?

A. There's more dissection. If there's an erosion into the bladder, I need to repair the bladder. And I have to get to the bladder somehow, so I either have to go in abdominally or go in vaginally to repair those erosions into

Page 138

those areas.
Q. And that's not like the simple office procedure?
A. That is not a simple office procedure. But once again, those are -- those do not happen commonly.
Q. In your experience, what's the percentage of the women that you implant with polypropylene slings that --
A. Sorry, can you start over again?
Q. Sure.
In your experience implanting polypropylene slings, do you have an estimate of how many women suffer from voiding difficulties after the procedure?
A. I don't have an estimate of my own.
Q. I may have already asked this.
In your experience doing the Burch procedure to treat incontinence, do you have an estimate of what percent of the women suffer from voiding difficulties after the procedure?
A. I don't have an estimate for

Page 139

that, no.
Q. Do you have some standard of what you consider an acceptable rate of voiding difficulty for a surgery to treat incontinence?
A. So, that's also a difficult question 'cause we need to understand what voiding dysfunction is, and once again is the voiding dysfunction symptomatic or not symptomatic. Many women's sometimes will just tell me their voiding pattern changes after you put a sling in. We're doing surgery on them.
So that's why I don't have a great estimate for you 'cause voiding dysfunction is really a hodgepodge of symptoms that a patient may have.
Q. What voiding difficulty symptoms would require surgical intervention?
A. So, if there's any evidence of obstructed voiding, that the sling has some reason -- for some reason got a little too tight around the urethra, or underneath the urethra as opposed to

Page 140

around it, I apologize, and if someone is complaining of difficulty urinating, she feels that she's got the urgency, it's a very slow stream, it's dribbling, she has urinary retention, that may indicate to me that this sling has gotten a little too tight for her and we need to go back to the operating room to do a revision or cut the sling.
Q. Do you have an estimate of how often the women that you implant these slings in have those obstructive voiding complications?
A. I have not done a systemic review of my patients.
However, I think I'm cutting about one sling a year, so it's about a half, maybe a half percent or something like that that I'm going back in, that I know of, on these patients.
Q. So maybe one out of approximately 175 slings per year that you implant the woman is going to develop some obstructive voiding problem; is that

Page 141

fair?
A. That's going to develop some kind of obstructive voiding problem that I need to go back in and cut the sling, yes.
Q. And that's because the sling had gotten a little too tight maybe around the urethra; is that correct?
A. Yeah. I pretty much put the sling in the same way. There's some people who develop more scar and there's some people who develop less scar. And yes, the sling has scarred in and gotten a little too tight underneath the urethra causing the obstruction, causing the voiding difficulty.
Q. And that's not because you put it in incorrectly, is it?
A. I don't think so. It's a known, commonly known complication for a midurethral sling. It's a commonly known complication for any type of anti-incontinence procedure that we're performing.
Q. And you put the sling in with

Page 142

the same --
MR. BENTLEY: Let me rephrase that.
Q. When you put the sling in, you always put them in tension-free, correct?
A. Correct.
And I understand tension-free is difficult. It's just like when we're doing obstetrics and we don't do traction on the baby's head.
So, tension-free is one of those words that we put in open and closed quotations.
Q. You don't put the slings in with tension; is that fair?
A. Try not to, yes.
Q. But sometimes though some of the women still develop obstructive voiding because the sling got a little too tight?
A. Correct, yes.
And once again, commonly known.
Q. Those women that you sling that develop obstructive voiding because the sling got too tight, when in your

Page 143

experience does that occur; what time frame after the implant?
A. Generally within the first year is I would see that.
Q. Doctor, could you please turn to page 7 of your report. We started talking about this a little bit.
I did it again, sorry. Page 50.
A. No problem. Going back.
Q. Going back forward.
A. Yes.
Q. All right. On page 50.
A. Yes.
Q. (Reading) "The most extensively studied surgical treatment."
Do you see that paragraph that begins with that?
A. Yes.
Q. A little bit down in that paragraph you say: "Symptomatic reviews of randomized control trials (Level I) provide the most reliable data followed by individualized randomized trails (Level II), cohort studies (Level III), provide

Page 144

lower quality of evidence, and finally case series provide the lowest (Level IV.)"
Is that correct?
A. Correct.
Q. Is that consistent with your approach to evaluating literature in your practice and in this report?
A. It is today.
Q. When you say "it is today," has that changed in your experience, or have you always considered Level I to be systemic or systematic reviews of RCTs?
A. I've always considered that, but there wasn't a lot of good Level I data available in the late '90s, and early 2000s.
Q. Right. So, the levels of data, the definitions of what Level I data, that's nothing new, right?
A. Yeah, I don't know when Oxford came out with it, but it's been available, yes.
Q. And all things equal, you would rather look at Level I data than Level II

Page 145

and Level III, correct?
A. Correct.
Q. What's your definition of Level II data?
A. Level II are individualized, randomized control trials, ones that may have not been so -- and ones that -- mostly randomized control trials and ones that maybe were poorly structured or may have had a large loss to follow-up. They're not as strong as the well-performed randomized control trials.
Q. Could well-performed large multicenter RCTs be Level I evidence?
A. It depends on what other data's available.
Q. And cohort studies are lower level of evidence, or Level III; is that correct?
A. Yes, cohort and case control studies are lower levels.
Q. So, when you're looking --
MR. BENTLEY: Let me rephrase that.

Q. When you are talking about, quotes, reliable evidence, quote, does that mean that you're looking for Level I or Level II evidence?
A. I'm always looking for Level I or Level II. If that doesn't exist, we need to go to the III and the IV.
Q. So, could you please turn to page 42 of your report.
A. Okay.
Q. In that middle paragraph that starts off: "I was an early adopter of TVT."
Do you see that?
A. Yes.
Q. Do you see about halfway down say: "I have seen reports and testimony from experts, including Dr. Bruce Rosenzweig, suggesting that both mechanically-cut TVT and laser-cut TVT are defective."
Do you see that?
A. I see that.
Q. The next sentence you put:

"These opinions are not based on reliable scientific data."
A. Correct, because later on in my report, and we can move to that page if you like, there is some data on mechanically-cut slings versus laser-cut slings which did not show any difference.
Q. So, just to be clear, in this sentence when you're talking about it's not reliable, you're not making a reference to whether or not it's Level I, Level II, Level III; is that fair?
A. I am not.
When I state that it's not reliable -- where does it say -- okay. I have searched -- there are no reliable clinical studies to back what he says, that I'm aware of. And when I say "he", it's Dr. Rosenzweig.
If you can produce some data that shows that mechanically-cut TVT and laser-cut TVT have any differences, I'd be glad to look at those.
Q. So you reviewed Dr. Rosenzweig's

report and reviewed the studies that he looked at and discussed, correct?
A. Yes. I don't have it committed to memory, but I did review his report. He's written a number of them.
Q. And you determined that the evidence he was looking at was not reliable scientific data, according to your report, correct?
A. According to my report, I did not find any reliable clinical data to support his claims.
Q. And the next sentence you discuss the Thubert 2016 study that showed TVT versus TVT-Exact had similar peri and postoperative complications.
Do you see that?
A. Yes, I do.
Q. Then you state: "Both TVT and TVT-Exact resulting in 0 percent mesh exposure"?
A. Yes, in that study.
Q. And you don't have any discussion of Dr. Rosenzweig's opinions or

data regarding laser-cut or mechanically-cut, in this paragraph at least, do you?
A. In this paragraph, I do not. I do remember Dr. Rosenzweig saying he has implanted about 50 or 75 midurethral slings, and I don't think he has anywhere near the experience that I do in implanting midurethral slings, nor the clinical experience.
Q. Okay. I'm not really talking about Dr. Rosenzweig's personal experience.
A. Okay.
Q. In his report he discusses some literature.
Do you recall reading that?
A. Yeah, he discussed literature.
Once again, if you want to pull out his report, I'm more than welcome to look at it with you, but I'm not going to remember it verbatim.
Q. And you came to the conclusion that his opinions were not based on

Page 150

reliable scientific data, correct?
A. His opinions were not based on any reliable data that I was able to find.
Q. So you looked at the data that he reviewed and cited to, correct?
A. I did my Pub Med searches in terms to try to find the differences between the TVTs and TVT-Exact and laser-cut and non-laser-cut, Boston Scientific meshes and not Boston Scientific meshes, and I tried to find the data where it said that mechanically-cut was any better or worse than a laser-cut.
MR. ROSENBLATT: He's asking if you reviewed the studies that he actually cited in the body of his report.
THE WITNESS: So, I went through his --
MR. BENTLEY: Thank you.
A. Okay. I went through the reliance list, and I actually went through some of the reports and studies from his reports.

Page 151

Do I recall if I remember seeing one on specific on mechanical and laser, I don't.
But once again, if we can pull out his study and see the citations, I'd be glad to review those would be.
Q. I'm just trying to -- there's nowhere in your report that I found that discusses your conclusion that Dr. Rosenzweig's evidence that he relied upon was -- I don't understand how you reached that it's not reliable.
A. Well, if we turn the page, we can look at studies by Lim and Agarwala.
Q. And that's not -- I appreciate that you're citing to some other evidence. I'm trying to see how you got to your conclusion that the evidence that Dr. Rosenzweig didn't rely upon reliable evidence, and if you have any opinion today as to your concern or criticism of the studies that Dr. Rosenzweig cited, can you share those with me, please?
A. I don't recall in the

Page 152

particulars.
But once again, if we pull out his report, I'm willing to go through that with you why I reached that conclusion.
Q. Okay. I believe you testified that you performed a Pub Med search, is that what you said?
A. Yes.
Q. And you performed a Pub Med search in response to Dr. Rosenzweig's laser-cut opinions?
A. No, I didn't put Rosenzweig in there because he hasn't written any scientific paper on this.
Q. Right.
A. I would have put in TVT complications. I would have put in mesh erosion, mesh exposure, mesh extrusion. I can't remember every single term that I went ahead and used in order to do my searches. And I would have tried to find what he did and where he based his opinions on and what I based my opinions on.

Page 153

Q. You have no record of what key word searches you've done?
A. I did not keep a running tab, no.
Q. We already talked about you didn't do a systemic literature review, correct?
A. No. I did my Pub Med searches and sometimes on Google Scholar, and then when I got to one paper, I would look at the references on that paper.
You should see my library room in my office. My wife ain't happy.
Q. You didn't have a preset inclusion/exclusion criteria?
A. What systemic searches and stuff like that?
Q. Correct.
A. No, I didn't write a paper and include that kind of stuff.
Q. Do you have any type of record of how many articles your key word searches turned up?
MR. ROSENBLATT: Object to form.

BY MR. BENTLEY:
Q. Do you have any reliable record of how many articles popped up in your Pub Med search when you did a key word search --
A. I don't remember, but I can tell you that I've been reviewing literature throughout my entire career. I've been reviewing the literature that's available on slings, on prolapse. I did an extensive search and even reviewed more literature and more articles, many of which I had seen in the past, for this particular report.
Q. Are there some studies that you found more powerful or compelling than others?
A. As I stated before, I always put more emphasis and I rely more on Level I and Level II data than Level III and IV if that data is available.
Q. And if you had any type of opinion as to which evidence was more powerful or compelling, would you have

provided those opinions in this report?
A. I would have tried, yes.
Q. And in this report you include a lot of data, correct?
A. I think I did, yeah.
Q. And is that data limited to any specific threshold of Level I or Level II?
How did you go about choosing which articles to put in here?
A. Once again, from my searches, if Level I data existed, I tried to include the Level I data. So with the highest level of data that existed for that particular topic, I tried to include.
Q. Doctor, would you agree that polypropylene mesh, once implanted, causes a chronic inflammatory reaction?
MR. ROSENBLATT: Object to form.
A. Any kind of foreign body that you're going to place in the body is going to create a foreign body reaction.
Q. Right. It's a little more specific.
The polypropylene slings that

we're talking about here, the TVT and TVT-Exact, once those are implanted, do they cause a chronic inflammatory reaction?
A. Yes, when you implant a polypropylene or any type of synthetic slings, or any type of synthetic material for that matter, you're going to get a chronic inflammatory reaction.
Although, polypropylene slings as compared to other slings have a -- seem to have a lower chronic inflammatory reaction than things that we used in the past.
Q. Do you have an understanding as to whether the construction of the mesh influences the level of inflammation?
A. Yes, I do.
Q. And what is that?
A. So, the pore size will matter. So you would like a pore size above 1 millimeter. You want a type 1 macroporous mesh that is monofilament as opposed to multifilament. So there are

characteristics of the fiber and there are characteristics of the knit that both, as well as the weight of density of the fiber, that come into play when you put a polypropylene sling in.
Q. Do you have an opinion as to whether or not the cutting method of the mesh influences the inflammation?
A. In my experience, the laser-cut and mechanically-cut have functioned the same and come to the -- and have provided the same results in efficacy as well as safety.
Q. My question is do you have an opinion as to whether the cutting method has any type of impact on the inflammatory response once implanted?
A. My opinion is that cutting or laser-cut does not make a difference.
Q. It doesn't make any difference to the inflammatory --
A. On the inflammatory response.
Q. Thank you.
So, you've testified that the

Page 158

polypropylene slings do have a chronic inflammatory reaction, correct?
A. Yes.
Q. So, if the inflammatory reaction was instead described as transient, would that be incorrect?
A. No, not necessarily, 'cause if you remember, or if you recall, or I'll tell you, there is two types of inflammatory reactions that occur. There's an acute inflammatory reaction and a chronic inflammatory reaction that occurs when you implant any foreign body. So the acute one is transient, goes away.
Q. So the chronic reaction is chronic, is that what you're saying?
A. The body responds to that foreign body that's placed in, whether it's a suture material, whether it's a polypropylene mesh. Generally these products are safe and don't -- don't cause complications. But yes, the body still knows that it's there. That part of the design was good. For the body.

Page 159

Q. So, if you were discussing the inflammatory response that happens after implanting this mesh in a woman's body, if you were discussing that with one of your patients, and this mesh is a permanent implant, correct?
A. Correct.
Q. It's in a woman's body until you take it out, correct?
A. It's intended to last and it's probably going to last longer than all of us.
Q. Because it's made of plastic, correct?
A. Correct.
Q. And when you're discussing whether or not to have this implant, do you describe the inflammatory response with your patients as chronic, or would you describe it as transient?
A. So, from what the patient is going to realize, 'cause the chronic inflammatory reaction is something that the patients don't realize that there's a

Page 160

chronic inflammatory reaction going on. So what I usually will discuss is with them the -- the acute inflammatory reaction, which is a little pain and vaginal discharge that you can get with these slings, as opposed to the, quote/unquote, chronic inflammatory reaction.
And, don't kid yourself, I tell every single patient that this is a permanent implant. This is not meant to go away. It is not meant to be removed if it is working.
Q. And if there's a problem, you still don't remove the whole mesh; you cut the piece that is sticking out and leave the remainder of the mesh, correct?
A. Once again, depends what the problem is. With slings, the most common problem is an exposure or retention. Then we would just either cut or remove that portion. We would not go after the entire rest of the sling because that just increases the morbidity to the patient

Page 161

with no gain.
Q. Have you, in fact, described the mesh as like rebar in concrete?
A. Okay. So, what I was describing is there, it's not like rebar in concrete. What I was trying to show over there, and you're going to pull out my picture, I got it. What I was trying to describe there is that the repair is a more durable type of repair.
And that wasn't to patients, by the way. That is meant to other physicians.
But the repair there is for the body to integrate into the mesh as the concrete integrates into the rebar.
Q. Using your analogy, how easy is it to remove rebar from concrete?
A. I have no clue. I've never done that.
Q. And how easy is it to remove mesh from the tissue once it's been incorporated?
A. Removing the slings, if it's an

Page 162

exposure, I don't find is a terribly difficult procedure, as I have mentioned in my report already. The more mesh you need to take out, the more procedure you need to go ahead and do. But removing the mesh, especially with sling mesh, you can remove what you need to get out.

Q. When you remove the mesh, do you necessarily remove the tissue that it's incorporated into?

A. So, when I remove the mesh, I try to not cut or damage any vital structures. So usually what I will be doing is cutting on the mesh itself in order to remove the mesh once I get a free end. I'm going to take my scissor or a scalpel to try to shave off and shave out the mesh and -- what was the question again?

Q. You lost me.

If you're treating an erosion into the bladder, for example, there's no mesh sticking out visibly, correct?

A. Correct.

Page 163

Q. And when you remove the mesh, you're going to cut out some tissue with it, correct?

A. A very small amount, yes.

Q. Because it's been incorporated, right?

A. The tissue in the interstices, or in the pores usually would come out.

Q. Because it's been integrated into the body, correct?

A. Correct.

Q. By design, correct?

A. Correct.

Q. I'm handing you what's been marked as Exhibit 5.

(Exhibit Winkler 5, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. This is one of the Power Points you provided to us prior to this deposition.

On page -- first of all, what is

Page 164

this Power Point, Doctor?

A. So, this was probably a talk or a grand grounds that I gave at some point in time in order to -- that I gave at some point in time.

Q. Would you have gotten paid to give this talk?

A. Not necessarily.

Q. And on page I think it's 3.

A. Okay.

Q. On the bottom right corner you have: "Mesh equals reinforced concrete."

Do you see that?

A. Yes, I do.

Q. And you have a picture with the rebar on the left and then the concrete on the right; is that correct?

A. Yes, I do.

Q. And that's the analogy you used to describe the mesh here; is that fair?

MR. ROSENBLATT: Object to form.

A. Well, once again, my analogy here is for integration and native tissue repair relies on your own tissues to

Page 165

support it.

We know that tissue has wear and tear on it, and the idea over here is that we're going to get a more durable and longer-lasting repair and have better efficacy if we go ahead and use that.

Q. If you go ahead and use?

A. And use that synthetic mesh or sling.

Q. That acts like a rebar in concrete?

A. I didn't say it acts like a rebar in concrete.

I said the philosophy behind it is that why is concrete stronger when you put rebar into it? Because you've got something that it sticks on to, right. So the same philosophy here is when you're going to put that mesh in, you've got your tissue to stick onto.

Q. It's an analogy you appropriately used to describe the integration of the mesh into tissue, correct?

A. Correct, but taking out the mesh is not equivalent to chiseling away on concrete.

MR. BENTLEY: I'm going to hand you what's marked as Exhibit 6, which is another one of the Power Points that you produced.

(Exhibit 6, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: I'm going to hand you what is marked as Exhibit 7, which is another Power Point.

(Exhibit Winkler 7, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: Here's Exhibit 8, which is another Power Point you produced.

(Exhibit Winkler 8, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of

this date.)

MR. BENTLEY: I'm going to hand you Exhibit 9, which is another Power Point.

(Exhibit Winkler 9, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: I'm going to hand you what is being marked as Exhibit 10, another Power Point produced.

(Exhibit Winkler 10, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: Exhibit 11 is another Power Point.

(Exhibit Winkler 11, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: We can just set these aside for now.

THE WITNESS: Okay.

MR. BENTLEY: Exhibit 12 is another Power Point.

(Exhibit Winkler 12, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: Exhibit 13 is another Power Point.

(Exhibit Winkler 13, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: Exhibit 14, another Power Point.

(Exhibit Winkler 14, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

THE WITNESS: Are we just going through all of them?

MR. BENTLEY: I'm just entering them for the record before I forget.

Exhibit 15.

(Exhibit Winkler 15, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: 16.

(Exhibit Winkler 16, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: 17.

(Exhibit Winkler 17, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

MR. BENTLEY: 18.

(Exhibit Winkler 18, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

(Exhibit Winkler 19, Power Point slide deck of Harvey Winkler, M.D., was marked for identification, as of this date.)

Page 170

BY MR. BENTLEY:
Q. Doctor, we've entered several Power Point presentations that you produced, and these Power Points, did you make these yourself, or someone in your office make them for you?
A. The slides?
Q. Yes.
A. I made them most likely myself. I don't remember going -- some of them are going years back, if anyone helped me or where I got the information from, but generally I try to make my own slides. Sometimes I do them with the fellows today.
Q. And these are all from presentations you gave?
A. In the past, yeah.
Q. Do you have any way to tell what dates these presentations were given on?
A. Honestly, no.
Q. If you could please turn to page 42 of your report.
A. Got it.

Page 171

Q. You state: "I was an early adopter of TVT which has been available in mechanically-cut in the United States from '98 to present, and I also used TVT laser-cut mesh, in addition to TVT-Exact (only available in laser-cut), and have not seen any noticeable difference in objective cure, subjective cure, or complications including mesh exposures, pelvic pain and dyspareunia."
Did I read that correct?
A. Yes.
Q. We've already discussed a little bit we don't have any reliable way to estimate how many of your patients had complications, correct?
A. I have never -- I haven't done a systemic review. Once again, I think my complication rate is lower than the literature.
However, I will tell patients when I talk to patients it's what's quoted in the literature.
Q. Because you don't have a case

Page 172

log; you don't track complications?
A. Correct.
Q. So when you say you have not seen any noticeable difference --
A. But I will tell you I think my complication rate is low 'cause, once again, I'm not seeing that many patients back that I'm taking back to the operating room in order to treat for a complication.
Q. Right. And my question is when you state in your report that you've not seen any noticeable difference in cure complications between the two meshes, is that simply based upon your review of the literature?
A. So, it's based on what I've seen in my patient population 'cause I switched from one to the other. I didn't see a noticeable increase or decrease complication rate and what I've reviewed in the literature.
And I've been using both for almost up 'til when AMS Astora went out of business because, if I remember correctly,

Page 173

their transobturator sling is a mechanically-cut sling. So I was -- I've been using mechanically-cut slings for years.
Q. And you don't cite to any study here that you don't have a difference between the --
MR. BENTLEY: Strike that.
Q. You don't cite to any study here indicating that TVT-R, machine-cut is the same as TVT laser-cut?
A. Well, I have the Thubert study, right.
Q. And the Thubert study looks at TVT-Exact, correct?
A. Versus TVT.
Q. Right, and we already discussed the TVT-Exact has different diameter trocars, correct?
A. We have discussed that, yes.
Q. And you don't cite any study specifically comparing TVT machine-cut to TVT laser-cut, correct?
A. Yeah, but we're not -- the

Page 174

trocars are not the issue here with the mechanical-cut and the laser-cut.

We're talking about the mesh, so what difference what trocar is attached to?

Q. What study do you have that compares TVT-R machine-cut to TVT-R laser-cut?

A. In terms of the mesh itself, we can look at the Thubert study.

Q. The Thubert study uses TVT-Exact, right?

A. Versus TVT mechanical-cut.

Q. And my question is using TVT Retropubic machine-cut as compared to TVT laser-cut, what study compares those two head to head?

A. I'm not aware of any study, but once again, I'm not aware of what the difference is on the mesh properties as opposed to what needles you're putting in to put them in there.

Q. On the Thubert study, you state that it is TVT versus TVT-Exact, correct?

Page 175

A. Yes.

Q. Do you know what percentage of the TVT cases in Thubert were machine-cut?

A. I don't recall, but I'd be glad to look at that literature if you have it.

In addition, if you look at Lim underneath that where they looked at mechanically-cut TVT slings to the 108 Advantage slings, the needles on Advantage slings were almost identical, or the trocars are almost identical to the TVT-R trocars. So there is some literature of comparable type of procedures.

Q. Comparable, but it's not exactly the TVT-R, correct?

A. It's not the TVT-R.

Q. Right. Doctor, you started using --

MR. BENTLEY: Strike that.

Q. You were trained on TVT Retropubic in Philadelphia around 1998 by Dr. Vincent Lucente, correct?

A. Yes.

Q. And do you recall that TVT

Page 176

Retropubic was initially a clear mesh?

A. Yes.

Q. And subsequent, Ethicon introduced a blue mesh that replaced the clear mesh, correct?

A. Yes.

Q. When Ethicon introduced the blue mesh for TVT Retropubic, are you aware that Ethicon received reports of blue particles in unopened packaging?

A. I'm aware of that today, yes.

Q. When did you learn that?

A. I learned that on my review of the documents that Ethicon had sent over to me, but I had looked at these meshes and seen these meshes and it's not something that overly surprised me that a particle may have been in there, especially in thousands of them that they produced.

Q. What if there was more than one particle, that didn't concern you?

A. No, it didn't concern me.

Q. It doesn't concern you that

Page 177

particles were falling off the mesh before it was even implanted?

A. I don't care what happens with the particles falling off the mesh implanted. Once that mesh was implanted, I don't believe that particles were falling off, and I don't think it made any difference clinically.

Q. What studies do you have to support your opinion that the particle loss stopped once it was implanted?

A. There's not going to be any study on that. No one's going to go back and look on it. But I don't have any studies, that I'm aware of, whether it's plaintiff studies or defense studies, that actually show complete breakage of mesh fibers in vivo.

Q. You don't have any studies to support your opinion that the particle loss stops after implantation.

Do you have any reason or explanation of why you think that the particle loss would stop after it's

Page 178

implanted?
A. Once you get tissue integration and once -- unless -- once you get tissue integration around that mesh, why would I assume that a piece would suddenly tear off?
When you hold the mesh and you put it down, it doesn't spontaneously come out. It's when you stretch it beyond its limits that it's intended to when I put it in surgically do we see that particle fray.
Q. Well, you know that unopened packages before it was implanted, there's some particles that fell off, correct?
A. I don't know if it fell off or if it fell off during the cutting. I don't know when it got into that box.
Q. But it's your reason that you intend to offer to the jury that the particle loss stops once it's integrated; is that correct?
A. I have no reason to believe that there are particles breaking off mesh once

Page 179

it's in the patient's body.
Q. And your explanation is because once it's integrated, it's not going to fall apart?
A. Well, you have tissues supporting around it. So you have other tissue that's bearing load here as well.
I have no indication that, and I do not believe that particles are mysteriously just breaking off.
Q. If they were, would that be a problem?
A. I don't think that would be a problem, to be honest with you. Unless they were clinically causing an issue for that patient.
We've been putting in these sutures for the longest time and you have little particles of suture and generally it doesn't cause a problem.
Q. Doctor, you say that mesh loses particles when it's elongated at the 50 percent elongation, in your report I believe on page 55.

Page 180

A. I would just like to comment we never stretch it out 50 percent when we're putting it in a patient.
Q. My question is in your report, you state that the mesh loses particles when it's elongated at 50 percent according to studies done by Ethicon that you cite in your report, correct?
A. Correct, on page 45.
Q. And it's your testimony that that's beyond the physiological range of elongation once implanted; is that correct?
A. That's correct.
Q. And then --
A. In my opinion.
Q. -- what's your opinion as to what the physiological range of elongation is once it's implanted?
A. I don't believe -- I don't have a great answer for you of exactly how long these meshes -- how long -- if -- if these meshes do elongate when they're in the body or they do stretch. I would think if

Page 181

they were elongating or stretching at a considerable rate, we would see a significant decrease in efficacy as time went on.
So, based on my clinical opinion, I do not have experience in these meshes -- in the midurethral sling meshes significantly elongating.
Q. In any of the plaintiff reports that you read, did you notice any of the evidence they cited discussing the physiological range of elongation of the mesh once implanted?
A. I have not seen any clinical data of how long these meshes are elongating. There's theoretical data of how they will react, but I do not have any solid clinical data to support any of that.
Q. I'm just trying to understand on page 45 you put you've seen the Ethicon Power Point relied upon by plaintiff's experts comparing the physical differences to TVT mechanical and laser-cut, and you

Page 182

put: "When stretched beyond the physiological range at 50 percent elongation."

What's your basis that that's beyond the physiological range?

A. So, that's going to be doubling the length of the sling. So, when I go in and if I have to do a mesh exposure or a mesh erosion or a tightening of the sling, I do not see stretching of that.

THE WITNESS: And Paul, do we have that picture of a sling that eroded?

A. There's a picture of a -- this is a -- this is it.

MR. ROSENBLATT: (Handing.)

(Exhibit Winkler 25, color copy of photograph, was marked for identification, as of this date.)

BY MR. BENTLEY:

Q. Doctor, I marked what is labeled as Exhibit 25, which is a picture you brought to the deposition.

And could you describe what this

Page 183

is a picture of?

A. This is a mesh exposure of what I think is a TVT sling, and we can see in this picture there's an exposure of the mesh into the vagina. And on exposures either I would see something commonly like this or -- and I don't see significant elongation in opening of these meshes and significant stretching of these meshes when I remove them. So there's no reason for me to believe that these meshes elongate up to 50 percent of their length.

Q. Let's talk about that a little bit.

It's a picture of an exposure which, by your definition, that's a externally visible piece of the mesh, correct?

A. Correct.

Q. And looking at this picture, do you have any way to determine what caused that mesh exposure?

A. No, I do not.

Q. Do you have any reason to

Page 184

believe that that mesh was incorrectly implanted by the implanting physician?

A. I would find it hard to believe that an implanting physician would leave a piece of mesh like that when he's implanting it.

Q. And the mesh exposure could develop postoperatively, correct?

A. Correct.

Q. And that could develop even if the implanting physician put it in without tension, as you do, correct?

A. We have agreed that that's a commonly known complication.

Q. That can happen even if it's implanted correctly, correct?

A. It can happen, yes.

Q. And we were discussing particle loss previously.

Do you remember that?

A. I do.

Q. And you wanted to discuss this picture in response to some of our questioning about particle loss.

Page 185

Do you remember that?

A. Yeah, I want to discuss this picture in response to elongation.

Q. Okay, thank you.

So, it's your testimony that because this picture doesn't show elongation, particle loss doesn't happen?

I'm trying to -- can you help me?

A. No. You asked me how do you know that elongation in the body does not happen above 50 percent. So I'm trying to give you an example of how I base that opinion on.

Q. So, if there was elongation, would you expect to see the mesh maybe roped?

A. I've never seen roping of the TVT mesh, and I know that people have described that.

What I usually -- if the mesh gets a little -- can get a little too tight, we're not going to see this kind of a picture. We're going to see more of

Page 186

that voiding dysfunction or difficulty urinating picture.

So, the interstices and pores are still there. It's just, yes, it does get a little, I don't want to use the word "roping." It can get tight you are under the urethra because it's scarring too much.

Q. But mesh can rope, you've read about that, right?

A. I've read about that, right.

Q. You don't have any reason to disbelieve people that have seen roped mesh, do you?

A. I don't have any disbelief in that.

My opinion is that when you get that roping, there may have been too much tension applied on the implanting portion of the procedure as opposed to all of a sudden the mesh roping upon itself.

Q. Have you seen bunched mesh in your clinical experience?

A. Yes, I have. And there are

Page 187

reports of mesh moving and migration and retracting. Nothing -- you can't a hundred percent guarantee that anything's going to stay in the place that you put it in.

MR. ROSENBLATT: I wasn't able to get my objection in in time. I don't know if you're asking about SUI or POP.

MR. BENTLEY: Sure.

BY MR. BENTLEY:

Q. Have you seen reports of mesh that's been implanted to treat incontinence of the mesh being roped?

MR. ROSENBLATT: Object to form.

A. I have not seen roping occur with a sling mesh.

Q. Have you read reports or literature that discusses TVT mesh that's roped after implantation?

A. I've read literature. I can't say a hundred percent if that literature was based on a midurethral sling or if that literature was based on meshes placed

Page 188

in for prolapse.

Q. When you're implanting mesh, if the stiffness of the mesh is different, does that affect the level of tension that is set during the implant?

MR. ROSENBLATT: Object to form.

MR. BENTLEY: That was awful.

BY MR. BENTLEY:

Q. If a physician is -- if you yourself are implanting a mesh and you've developed a technique to implant it such that there's minimal tension put on it, correct, and that's your intended goal when you're implanting the mesh is to have tension-free, correct?

A. Correct.

Q. If the mesh is stiffer than what you've been accustomed to, does it change how you have to set the tension of that mesh?

A. I don't know how to answer that question, to be honest with you.

Q. If you have a mesh that's stiffer than the one you've trained on

Page 189

that you're accustomed to, does that need to change the forces to be applied during implantation?

A. Once again, I don't know the answer to that question.

I would have to see the product, look at it. I would do a cadaver lab on the product. I would like to see data on the product before I went ahead and implanted it at this point in time.

Q. Do you have an opinion as to whether the stiffness of the mesh has any clinical significance?

MR. ROSENBLATT: Object to the form.

A. I don't know how to answer that question in terms of if we're talking about sling meshes, POP meshes. And even if you probably then separate them out, I wouldn't know how to answer that question for you.

Q. With respect to slings that are implanted to treat incontinence, do you have any opinion as to whether a stiffer

Page 190

mesh has clinical significance?
A. Well, a stiffer mesh, it's stiffer for a reason. So why don't we break it down into what the reason is?
Q. Yeah, I'm just trying to get an answer to that specifically, and then we'll break it down from there.
Do you have any opinion as to whether or not a polypropylene sling mesh that's implanted to treat incontinence, if the mesh is stiffer, does it have a clinical significance for the patient?
MR. ROSENBLATT: Object to form.
A. Once again, I really don't know how to answer that question for you.
MR. ROSENBLATT: What do you mean by "stiffer"? Maybe that might help.
MR. BENTLEY: Well, it's the words -- well, we'll get to it.
BY MR. BENTLEY:
Q. Do you want to turn to page 44 in your report?
A. Sure.

Page 191

Q. You state: "Neuman 2011 suggested that the stiffer TVT Secur laser-cut might have caused the de novo dyspareunia."
Do you see that?
A. Yes, I do.
Q. Okay. So what do you mean by "stiffer mesh"?
A. So, the laser-cut made it a little less, quote/unquote, stretchy at that point in time, in my opinion. And I did not think that that stretchiness made a difference from when I implanted the slings for TVT. If you are going to give me another sling, I'd have to see why it's stiffer.
Q. So, here you cite a study that suggests that the stiffness might have actually caused de novo dyspareunia; is that correct?
A. And that's with TVT Secur, which once again is an entirely different procedure, and placement for that is entirely different. So I will cite what

Page 192

they suggested.
Do I think that that's going to happen with a TVT? No. The implantation of a TVT Secur, entirely different than any type of the slings than what we're talking about right now.
Q. As you sit here today, do you have any criticism or critique of the Neuman 2011 study?
A. I mean, I think we're comparing Secure to TVT-O. I was not a big Secur user, as we discussed in the past. So, if we want to go through criticism particularly, we're going to need to pull out that study, 'cause once again, I don't remember it word for word.
Q. So you don't think that Neuman is really relative to the discussion of whether or not a stiffer mesh can cause clinical implications for the patient?
A. Well, especially if we're going to talk about TVT Secur and TVT-O, a transobturator sling, in my opinion, is going to have a slightly higher

Page 193

dyspareunia rate risk than a retropubic sling.
Q. And I guess my question is then why do you include this in your TVT report?
A. It was literature that I found. I didn't want to not include it at that point in time.
Q. In your report, you don't provide any analysis of why you discount the study, correct?
A. There's nothing more in my report about this, yes.
Q. And as you sit here today, you don't have any analysis as to why you discount this study, do you?
MR. ROSENBLATT: Object to form.
If you want to pull it out, he could provide his criticisms of it.
A. Yeah, I mean, once again I said that before. If we want to criticize, I can remember what I wrote. I can't remember what's in the paper.
Q. And I can only read what you

Page 194

wrote, right?
A. Right.
So, I'm not saying that -- that it's proven. It's suggested and we're not going to hide that.
Q. Do you disagree with their suggestion?
A. With their suggestion?
Q. Do you disagree with Neuman's suggestion that stiffer mesh might have caused de novo dyspareunia?
A. Once again, I will not comment. I am not a Secur expert whatsoever. I am not a TVT-O expert whatsoever. So I don't think my -- I'm an expert on transobturator sling, but on the TVT-O device, I never used that. So I would refrain from giving an expert opinion on either of these two products.
Q. So you're an expert on TVT Retropubic classic machine-cut; is that fair?
A. So, I'm an expert on these slings. I'm not an expert on putting in

Page 195

the TVT-O.
MR. ROSENBLATT: That's not a requirement for your expert, sir?
Strike that.
BY MR. BENTLEY:
Q. I'm trying to figure out --
A. I never put a TVT-O in. So how -- I don't want to really comment on the procedure.
Q. And you wouldn't want to comment on the safety profile of the TVT-O, correct?
A. I think the TVT-O is a safe procedure. I didn't say that it's not a safe procedure.
I just said I would reserve offering an expert opinion on placing it and anything with dyspareunia.
Q. Right.
A. I'm an expert on the complications of the TVT-O. I'm an expert on what's in the literature on the TVT-O. I'm an expert on how to implant the TVT-O, but since I have never done it, I would

Page 196

refrain from offering an expert opinion particularly on TVT-O.
Q. And in your TVT and TVT-Exact report, you discuss the Neuman study, correct?
A. Yeah.
Do you mind getting the study?
Q. And in your report, you note that they suggested that a stiffer mesh might have caused de novo dyspareunia; is that correct? Is that in your report?
A. Correct.
Q. As you sit here today, do you have any study or evidence to indicate that a stiffer mesh doesn't cause de novo dyspareunia?
A. I don't have evidence that a stiffer mesh causes more or less de novo dyspareunia.
They're suggesting it, and this is one study, in, let's see, how many people again?
Q. The question, do you have any evidence that indicates contrary to what

Page 197

you cite in your report, do you have any evidence suggesting that, contrary to Neuman, that stiffer mesh does not cause de novo dyspareunia?
A. I didn't say that a stiffer mesh is. The TVT Secur stiffer mesh.
So, how do you know it's the mesh and not the implantation technique?
Q. Doctor, my question is very precise.
Do you have any evidence as you sit here today that a stiffer mesh does not cause de novo dyspareunia?
A. I don't have any evidence that it causes more or less de novo dyspareunia.
I have one study that you just pointed at of 79 patients in a different type of procedure than we're discussing today that may suggest it.
Q. Doctor, do you hold yourself out as an expert on FDA regulations?
A. I am an expert on FDA regulations when it comes to devices and

Page 198

implants for incontinence as well as for the pelvic floor, in my opinion.
Q. Do you consider yourself an expert regarding FDA requirements for product labeling?
A. I'm aware of what's required in the -- I am aware of what's required in product labeling for devices, yes.
Q. What's required in product labeling?
A. So, any type of -- first of all, you need to explain the indication for what should be in the product label. You should try to explain who the device should not be implanted in, and then you would try to describe adverse events or complications that are specific to the device when used in that procedure the device is indicated for.
Q. And what's your basis for that definition?
A. I have read the, I think, the CFR, CFR Rule 21.
Q. The entire chapter?

Page 199

A. No, I skimmed it. I'm not going to remember it word for word.
Q. How did you decide which sections to skim?
A. I don't recall how I decided which ones I thought were more pertinent to others.
Q. Did you review the 21 -- did you skim the 21 CFR in preparation for this report?
A. Yes, I did.
Q. In your report, you discuss the IFU. Let's turn to page 22.
As we discussed, throughout your report you include a number of citations to footnotes; is that correct?
A. That's correct.
Q. And on page 22, you have a paragraph that begins "Furthermore."
Do you see that?
A. Yes.
Q. And the second to last sentence you put: "An IFU must give surgeons the ability to individualize the procedure and

Page 200

surgical management to each and every unique patient."
Do you see that?
A. Yes, I do.
Q. What's your basis for that opinion?
A. I don't rely on IFUs, nor should any surgeon rely on an IFU on how to do a surgical procedure. I don't rely on a company to teach me the surgical procedure in its entirety. I don't rely on an IFU to teach me that procedure. Nor do I rely on an IFU to tell me the commonly known complications of a procedure.
Q. So, your basis for that opinion is your personal experience and your personal practice with regards to IFUs?
A. Well, it's my personal practice. It's my discussion with other doctors.
There was a recent abstract that shows that, was it Frommer, she's in Hackensack. I can't recall the name. That actually shows that up to 40 percent of doctors don't even read IFUs.

Page 201

Q. Okay. But as you sit here today, you can't tell me one of the CFR sections that you skimmed that supports your opinion; is that correct?
A. Can you show me the CFR?
MR. ROSENBLATT: Object to form.
That mischaracterizes.
BY MR. BENTLEY:
Q. Doctor, what CFR section supports your opinion that an IFU must give surgeons the ability to individualize the procedure and surgical management to each and every unique patient?
A. I don't recall by heart.
Can we see the CFR?
Q. You don't know it and it's not in your report; is that fair?
A. I didn't say that.
MR. ROSENBLATT: Can I show him his reliance list?
MR. BENTLEY: Please.
A. But I'm not going to remember the report.
What I will tell you is --

Page 202

MR. BENTLEY: Actually, counsel, he's got the reliance list right in front of him.

A. What I will tell you is the way that we train doctors and the way we learn is throughout medical school, throughout residency and throughout fellowship, there are certain basic requirements that we need to teach. We teach our residents, our fellows to individualize the surgical procedure for the patient. We don't pick a procedure and then find the right patient for them. We teach them the risks, the benefits, the contraindications of specific procedures, and we also teach them the adverse reaction to the surgical procedures that we do. So we don't use an IFU to teach us how to do surgery.

Q. For your reference, Doctor, you have your reliance list in front of you. It's Exhibit 4.

A. Yes.

Q. And that Exhibit 4 is your reliance list that you reviewed in

Page 203

preparation of this report?

A. Yes.

Q. On page 2 the top there's a CFR cited.

A. Yes, I do.

Q. Is that your basis for this opinion regarding what the requirements of the IFU are?

A. I don't remember -- that's the reclassification for surgical mesh. That is not what the requirement of what needs to be in a IFU.

Q. Okay.

A. Is it?

Q. So, I believe the next CFR reference you have in here is the third or fourth last page and at the top it's got July 25th. I can tell you it's the fourth from the back.

A. 21 CFR 801?

Q. 109 subsection C.

A. Yes.

Q. Is that your basis for the opinion in your report?

Page 204

A. That's what I put in the reliance list.

Once again, I need to see 109(c) to definitely confirm that.

Q. Do you have any training in interpreting federal regulations?

A. I have training in using devices. I've had training in developing devices. I've had consulting train -- I've done consulting work with -- with industry in order to do device improvements, device development, new devices. I have written and signed off on clinical evaluation report. I have been teaching on IFU complications what are commonly known and what are specific to devices throughout my entire career.

Q. My question was specific to the federal regulations that govern labeling.

A. I'm not --

Q. Have you had any training regarding the federal regulations 21 CFR 801?

MR. ROSENBLATT: Object to form.

Page 205

A. We discuss -- we have had training in terms of complications from surgical procedures. It is not the -- we don't -- we are concerned, and the doctors are concerned of the common complications and we want to teach those as opposed to regardless of what the government regulations are of what needs to be included or what does not need to be included, we want to teach what the complications, adverse events are, regardless if the government requires it or not.

Q. Do you consult with companies regarding compliance with federal regulations?

A. I have been to the FDA and have consulted with a company regarding 522 study and some regulations regarding that.

Q. What's a 522 study?

A. So, a 522 is a post-market study ordered by the FDA on devices.

Q. When are those ordered?

A. Usually they're ordered after a

Page 206

device has been on the market.
Q. In what situations are 522 orders requested?
A. It's when the FDA decides that they need more information on a device, it's my understanding.
Q. If you could please turn to page 40 in your report.
A. Okay.
Q. The bottom paragraph you wrote: "The TVT IFU appropriately warned surgeons of the potential adverse reactions specific to the device, including damage to vessels, nerves, bladder, urethra or bowel, as well as the possibility of extrusion, erosion, fistula formation or inflammation."
And my question is your opinion that the TVT IFU appropriately warns, is that based upon your experience as a physician or your interpretation of a specific federal regulation governing labeling?
A. It's my interpretation of the

Page 207

CFR that says you do not need to include commonly known adverse events.
Q. And which CFR is that again?
A. You have to remember -- it's CFR 21. I don't remember the exact number.
Q. So, it's your testimony and your opinion that you intend to offer at trial that Ethicon's IFU was in compliance with the applicable 21 CFR 801 in governing product labeling? That's your opinion?
A. That's my understanding, yes.
Q. And that's what you seek to testify to at trial regarding your opinions, that the TVT IFU appropriately warns?
A. There's nothing in that IFU that I don't think I knew beforehand that's specific to the TVT device except for the exposure or erosion with a synthetic mesh.
Some of the stuff -- some of the commonly known chronic pelvic pain or dyspareunia can happen with any surgery. It can happen with any particular type of vaginal surgery we do, and it can happen

Page 208

with any kind of surgery that you have anywhere in your body, develop chronic pain at that site.
MR. ROSENBLATT: And I don't mean to interject on the record, but to the extent Judge Goodwin does not allow FDA testimony at trial, we would not be offering him as an expert on FDA regulations, but for purposes of explaining his opinion, we'll offer him.
BY MR. BENTLEY:
Q. And your basis for saying the TVT IFU appropriately warns is based upon your review of the applicable 21 CFR 801, correct?
A. It's based on my review of multiple -- of my knowledge of the procedure. It's based on my knowledge of how we train our residents and what we inform our residents. It's based on my knowledge of continuing certification for our doctors at this point in time, and it's based on my reliance that device

Page 209

companies do not and should not be teaching surgeons on how to operate and who -- and who are not the right patients on it. They can give their opinions, but it's ultimately the surgeon's decision.
Q. Okay. So, your standard for what an appropriate IFU warning is, is that based upon your review of the federal regulations, or is that just your personal opinion?
MR. ROSENBLATT: Object to the form.
I think he just explained that it's both his --
MR. BENTLEY: I'm more confused now than I was to start.
THE WITNESS: I'm sorry.
BY MR. BENTLEY:
Q. Is your opinion that the TVT IFU appropriately warns, is that opinion based on your review of federal regulations, or is that based upon your personal opinion as a physician?
MR. ROSENBLATT: Object to form;

Page 210

asked and answered.
A. It's based on both. It's based on my review, as well as the way in my clinical experience and my teaching experience we have trained our fellows, trained other medical students, trained our residents. I may discuss complications that aren't in an IFU with a medical student, resident or fellow based on specific to the surgical procedure that we're performing.
Q. Have you reviewed any guidance documents that the FDA has put out regarding their interpretation of the labeling statutes?
A. I think I have.
Can we show what we're talking about?
Q. Well, first do you know guidance documents are put out by the FDA?
A. Yeah, I went on the FDA Web site. I've seen some of the stuff. I've done some searches.
Q. And in interpreting FDA

Page 211

regulations, it's important to review their guidance on how to interpret it, right?
A. If you're going to be writing an IFU, I think it's important to review the regulations.
Q. Including the guidance documents put out by the FDA?
A. I would try to review all documents if I was doing that.
Q. And to reach an opinion regarding the adequacy of the warnings that are required per federal regulations, it's important to review the guidance documents that are put out by the FDA, right?
MR. ROSENBLATT: Object to form; mischaracterization that a guidance documents equals what are required.
MR. BENTLEY: That's fair.
BY MR. BENTLEY:
Q. You can answer.
A. I would review the official rule, and I can interpret it as per the

Page 212

ruling.
Q. You can interpret it contrary to what the FDA guidance document would put out?
A. No, what the FDA rule says is what I need to follow.
Q. So you could just discount their guidance?
A. You can't discount their guidance. But I don't -- I'm not a lawyer, so, but I need to follow the rule and I need to -- the guidance can guide me on how to follow their rules.
Q. So, your opinion is that the IFU is adequate because it lists --
MR. BENTLEY: Let me rephrase that.
BY MR. BENTLEY:
Q. You think the IFU is appropriate because a lot of these complications are commonly known; is that fair?
A. They're commonly known to the physicians, yes, performing these procedures.

Page 213

Q. Do you know whether or not the FDA guidance documents instructs companies to warn about hazards including the severity or likelihood of the adverse events?
A. I think companies need to report on adverse events that have been reported with their devices and assess these reports.
Q. And that wasn't exactly my question.
Do you know whether or not FDA guidance documents providing guidance on how to interpret 21 CFR 801, do you know whether or not those guidance documents instruct the adverse events should discuss the severity and likelihood of the hazard?
A. Do you have it in front of you? Can I see it?
Q. I'm just asking you as you sit here.
A. So, I'd like to see the document in order to remember it.
Q. It's your opinion that the IFU

Page 214

appropriately warns, correct?
A. I've answered that.
Yes, correct.
Q. And you don't in your report discuss whether or not you have to warn about the severity or likelihood; is that correct?
A. I report what the complications are. I'm not aware of any numbers that need to be reported.
Q. Well, for example, death is a potential complication of any surgery; isn't that correct?
A. That's correct.
Q. But it's highly unlikely with most surgeries, correct?
A. Correct.
Q. But if death was actually more likely with one procedure compared to other ones, that would be important information to be in a label, wouldn't it?
MR. ROSENBLATT: Object to form.
A. I mean, death is a really serious complication that we're discussing

Page 215

here at this point in time. So, I think intuitively every patient knows that complications can occur, and death can occur with any surgery or any point in time, unfortunately.
Q. Okay. And if death, which can occur with any surgery, if the occurrence was more frequent with one product, do you understand that the manufacturer would have an obligation to warn about the increased frequency of that hazard?
MR. ROSENBLATT: Object to form.
What do you mean by "more frequent"?
A. And I don't -- are you talking about a procedure? Are you talking about a product? I'm not aware of --
Q. We're talking about products and your opinions in the report that they appropriately warn in the IFU.
And you're saying that these complications are commonly known, correct?
A. Correct.
Q. If it's not commonly known that

Page 216

a complication actually has an increased frequency with one product compared to another one, assuming that, do you understand that manufacturers of products have an obligation to actually share that frequency information with people?
MR. ROSENBLATT: Object to form.
A. I got to be honest, I don't understand the question.
Q. Right.
A. It's long.
Q. If you had reviewed the guidance documents, would you include them in your reliance list?
A. If I remembered to, yes, I would have included it.
Q. In your report you state: "There's no overt need to describe the possibility of chronic pelvic pain or dyspareunia because, as stated previously, their inherent risk to surgery, and vaginal surgery in particularly, which are commonly known."
What's your basis for opining

Page 217

that the labels are adequate if there's an increased frequency that people are not commonly aware of?
MR. ROSENBLATT: Object to form.
A. I think anyone doing these procedures knows that chronic pain or dyspareunia can happen. Anything in the vagina, anything that we -- any kind of surgery that we do can cause the possibility of dyspareunia and chronic pelvic pain can happen with any particular surgery.
Q. So it's your opinion that the IFU doesn't need to warn about anything?
MR. ROSENBLATT: Object to form; mischaracterization.
A. The IFU should warn, in my opinion, IFUs should warn about adverse events specific and unique to that product, not necessarily the procedure.
Q. And what are the adverse reactions that are specific to the TVT and TVT-Exact?
A. In my opinion, all you need to

Page 218

put in that -- if I was writing the regulation, I think that what's specific to TVT and midurethral slings is the risk of, and synthetic slings, is the risk of exposure and extrusion.
Q. And that's all you would put in the IFU based upon your understanding of the federal regulations?
A. No, I didn't say that and you didn't ask me that. I said if I was making the regulation.
So, the regulation is of what needs to be specific to that procedure and unique -- no, specific and unique to the device, not necessarily the procedure.
Q. So in your opinion, what needs to be in the IFU for TVT and TVT-Exact regarding adverse events?
MR. ROSENBLATT: Object to form.
I just want to make sure you're not asking about contraindications?
MR. BENTLEY: I said adverse events, right.
A. What's required by the CFR.

Page 219

Q. That's not my question.
In your opinion as a expert in this case that's offering the opinion that the TVT IFU is appropriate and adequately warned, in your opinion, what adverse events need to be in the TVT and TVT-Exact?
A. In my opinion, from what was known at that point in time, the IFU was adequate.
Q. I didn't ask that.
In your opinion, as you sit here today with the knowledge you've got, what adverse events need to be listed in the TVT IFU and the TVT-Exact IFU?
MR. ROSENBLATT: Object to form; asked and answered.
He said mesh erosion and exposure and that was it.
MR. BENTLEY: He hasn't answered -- you can look at the transcript.

BY MR. BENTLEY:

Page 220

Q. Do you know the question?
MR. ROSENBLATT: Can we go back and read that where he answered "mesh erosion and extrusion"?
MR. BENTLEY: I don't mean to belabor this. I'm going to keep going. I know he hasn't answered.
BY MR. BENTLEY:
Q. As you sit here today --
MR. ROSENBLATT: Hold on. I just want to hear what the previous question and answer was, Greg. I'm not trying to be rude and interrupt.
If you want to spend more time on it, I just want to make sure that he already did.
MR. BENTLEY: He's going to say two things. We've already spent more time talking about it than the actual answer would be if you'd give the answer.
MR. ROSENBLATT: I think he did give the answer. I just want to try to figure it out here.

Page 221

(The requested portion of the record was read by the Court Reporter.)
MR. BENTLEY: He's talking about writing the regulation. I didn't ask about writing regulation.
MR. ROSENBLATT: Fair enough.
MR. BENTLEY: Would you read back my question, please?
(The requested portion of the record was read by the Court Reporter.)
A. So, in my opinion, the adverse events that need to be there are -- include damage to vessels, nerves, bladder, urethra or bowel and the possibility of extrusion, erosion, fistula formation or inflammation.
Q. Are all of those complications unique to the TVT and TVT-Exact?
A. No, they're not.
Q. So what's your standard for what needs to be in the IFU?
A. My standard for what needs to be in the IFU is based on the government guidelines. Or, if I can correct,

Page 222

government regulations as opposed to guidelines.
Q. Do you hold yourself out as an expert in biomedical engineering?
A. I hold myself out as an expert when it comes to polypropylene and synthetic materials and their biocompatibility when placed in the pelvic floor.
Q. Have you ever designed a mesh?
A. I've discussed mesh properties with industry, but -- I've discussed different mesh properties with industry and how to design some meshes that we may be doing research on.
Q. And are you doing research on partially absorbable meshes?
A. Yes. And there's going to be some confidential information that I'm not going to be able to share.
Q. What's the purpose of researching partially absorbable meshes?
A. What's the purpose of resourcing -- to see and try to find out

Page 223

if there is a different option for patients using a partially absorbable -- an absorbable mesh as opposed to a permanent mesh.
Q. And what's the potential benefit of a partially absorbable meshes?
A. The potential benefit is that this mesh gets absorbed and it does not stay there forever.
Q. And what's the ultimate clinical outcome that that could potentially be for a patient?
MR. ROSENBLATT: Object to form. I just want to make sure that we're talking about incontinence.
MR. BENTLEY: Yes.
A. Talking about incontinence, so, we know that there is a long-term risk of placing in a polypropylene mesh. We know that although on the short-term most of the complications happen, you can get long-term complications as well. And if we can reduce that complication rate, mind you with the same efficacy, then there

Page 224

would be a benefit. But there's no proof at this point in time, there's no clinical data at this point in time that an absorbable mesh would provide that efficacy, nor is there any clinical data that the absorbable mesh that we're working on for slings would be a safer option for them.
Q. You're working on absorbable mesh for the treatment of incontinence; is that correct?
A. No. We're working on properties of absorbable mesh in rabbits, so, and comparing that to polypropylene.
Q. And are you testing inflammation in the rabbit? Or what's your endpoint?
A. There are multiple endpoints to the --
MR. ROSENBLATT: Object to form. To the extent you can discuss it and it's not confidential, you can answer.
A. There are multiple endpoints to -- in the protocol. I can't go through

Page 225

all those right now, nor do I remember every single one of them.
Q. As a physician and an expert in this case, what endpoints would you look for in researching a model involving partially absorbable mesh versus permanent mesh?
A. So, some of the things that I may look for will be inflammation, chronic foreign body reaction that we discussed, tissue strength, histopathology. This is --
Q. Do you consider yourself -- I'm sorry, were you done?
A. This is a very early study, obviously.
Q. Do you consider yourself an expert in histopathology?
A. I have reviewed -- when I have reviewed slides on the pelvic floor, I've reviewed slides with pathologists. I've done this ever since I was a medical student. I have -- I will be reviewing the slides from these rabbits that will

Page 226

come out, and I've been reviewing that throughout my career.
Q. You'll personally be reviewing the slides, or you're going to send them to a pathologist for their review?
A. Well, we're going to review them with them.
So, I'm not a board certified pathologist, but I've been looking at slides throughout my entire career an consider myself somewhat of an expert.
Q. Why don't you order -- why do you only order a gross specimen review when you send something to a pathologist that's been explanted?
A. There's no other benefit to the patient, and I would not want in order to go any further. What benefit would she get out of me after taking out the mesh, as opposed to spending the insurance company's money?
Q. What is the clinical significance, in your opinion, of a mesh roping?

Page 227

MR. ROSENBLATT: Object to form.
A. The clinical significance if a mesh ropes?
Q. Yes.
A. So, if it -- if that mesh ropes, it can then get too tight and get too tense and migrate into structures that we don't want it to go in. It can create increased scarring if it ropes.
Q. How does roping mesh cause increased scarring?
A. So, if -- you may -- with a roping mesh, you may get a band-like effect in the vagina, and I would attribute that to scarring. It's not like -- I would attribute that to scarring.
Q. Does the mesh roping and curling affect the pore size?
A. It may, but I will tell you I have not seen mesh roping and curling. I know it's been reported. I've not seen that with midurethral slings.
Q. If the mesh ropes and curls and

Page 228

makes the pores collapse, do you have an opinion as to whether that causes shrinkage and contraction?
MR. ROSENBLATT: Object to form.
Are you asking a hypothetical?
BY MR. BENTLEY:
Q. If you know.
A. Say that again.
Q. If the mesh ropes and curls, thereby causing the pores to collapse, does that cause shrinkage and contraction?
MR. ROSENBLATT: Object to form.
A. What I understand is that if the pore size theoretically is less than a certain size, you may get increased scarring.
Q. And that can happen through roping, correct?
A. I wouldn't say roping. It -- I would say it can happen through pore collapse.
If it ropes, it still doesn't have to collapse the pore, right?
Q. If you want to look on page 22

Page 229

of your report, Doctor, you have a paragraph that starts out "However."
A. Okay.
Q. You say: "Additionally, when placing the sling and moving the plastic sheathes, as directed in the IFU," you state: "averts the mesh from roping and curling, thereby keeping the pores open which prevents shrinkage and contraction."
A. Yeah, and I think I already stated that I do not see roping and curling occurring with midurethral slings.
Q. Maybe I just don't understand.
Your opinion is that roping and curling causes the pores to collapse, correct?
A. I said roping and curling may cause the pores to collapse.
Q. Okay. And if the pores collapse, that can cause shrinkage and contraction, correct?
A. I don't think the mesh shrinks. I think that you can get increased scarring if the pores collapse.

Page 230

Q. If the pores collapse, you can get increased scarring, is that what you testified to?
A. If the pores collapse or if you have small pores, there may be increased scarring.
Q. Okay. And increased scarring leads to shrinkage and contraction, correct?
A. Increased scarring may lead to shrinkage and contraction.
Q. And I mean, you're stating here in your report that's what the importance of having open pores is; is that correct?
A. I'm not going to -- you want to put that mesh in that the pores stay open, yes.
Q. Do you have any studies that provide measurements of what the pore size is after it's been implanted?
A. I don't have any particular studies, but I can show you a picture of, and we can show it later, of a picture of a transvaginal mesh that is seen

Page 231

abdominally without any evidence of pore collapse.
THE WITNESS: Want to pull that picture out?
MR. ROSENBLATT: He's got it over there.
MR. BENTLEY: I want to stick with slings right now because we're in the sling report.
A. So, I mean, we're not taking out slings with patients who are doing well with them, so you're not going to find that.
Q. If you could please turn to page 27.
A. Okay.
Q. You have a paragraph that starts "As a result."
Do you see that?
A. Yes.
Q. You say: "The TVT mesh is a suitable and currently one of the most appropriate mesh implants for the treatment of SUI."

Page 232

Did I read that correctly?
A. Yes, you did.
Q. And you stand by that opinion, right?
A. Yes, I do. And it's also backed by the nice study in the UK that I think that came out from 2014.
Q. And you state: "It's a suitable and one of the most appropriate meshes."
Right?
My question is what other suitable and appropriate meshes exist right now?
MR. ROSENBLATT: Object to form.
You're asking about --
MR. BENTLEY: The sentence in the report.
MR. ROSENBLATT: But you're asking about incontinence right now?
MR. BENTLEY: I'm asking in this sentence he says that the mesh is a suitable and appropriate mesh for implant for the treatment of SUI.
BY MR. BENTLEY:

Page 233

Q. My question is what other products are suitable and appropriate for the treatment of SUI?
A. So, the most two suitable ones that I'm aware of right now are the TVT mesh as well as the Boston Scientific Advantage mesh for slings.
Q. Do you have any understanding or appreciation of the difference in those two meshes?
A. They are very similar. We can pull out the Moalli study that I think has that in there. But they are very, very similar in terms of I think the mesh fiber thickness is exactly the same, and it could be that the Boston Scientific pore size is slightly less, but it's above 1 millimeter. And I think the Caldera slings are appropriate as well, but they don't have the same long-term data behind them as the two others do.
Q. And those are three different mesh constructions, correct?
A. Well, the Boston Scientific

Advantage and the TVT are extremely similar.

Why don't we pull out the study and take a look?

Q. I'm just trying to understand your sentence here.

A. So, I'm saying --

Q. Obviously the mesh knitting is a different design for different manufacturers; isn't that correct? It's proprietary design?

A. Correct. Correct.

Q. And that's going to necessarily make different pore size, albeit you're saying fairly similar, correct?

A. Mm-hm.

Q. And that's going to create different mesh weight, correct?

A. It may create different mesh weight, yeah, the total weight.

Q. And the mesh geometry or knitting design will create a different flexibility property, correct?

A. It can, correct. And if I

recall, the Boston Scientific mesh and the Advantage mesh, they're both a hundred grams per meters -- per centimeter squared. They're both a fiber of .15 millimeters, and the main difference is their pore size.

Another difference in the midurethral portion is it's heat-sealed and it hangs on the other side.

Q. And they're going to have different tensile strength based on their knitting, correct?

A. Yes.

And if we can look at the Moalli study, it probably has tensile strength in there. I don't remember that.

MR. ROSENBLATT: You have it in your report.

THE WITNESS: Yeah, but is tensile strength in there? I'm not looking.

MR. ROSENBLATT: You have it on page 26.

THE WITNESS: Okay.

MR. BENTLEY: I mean, I don't have a question pending.

MR. ROSENBLATT: Sure.

BY MR. BENTLEY:

Q. Doctor, what's your definition of "state of the art"?

A. I don't know if I have a total strict definition of "state of the art." I think state of the art is what is considered the best procedure that we have available at the time.

Q. What's your basis then for saying the design of the TVT is state of the art?

A. I think that right now, the design of the TVT was a revolutionary concept and it is one of the standards that other slings should be compared against or the data on that type of sling should be compared against if you're going to change.

Q. So, the mesh in the TVT, is that mesh specifically, the design of that mesh, is that the state of the art of the

mesh?

A. I think the whole procedure was a state of the art procedure. It was a, you know, totally different concept and it changed the way we treat stress urinary incontinence in this country.

Q. So, I think I understand, the design of the TVT procedure itself, in your opinion, that's state of the art?

A. It was state -- yes, it's state of the art.

Q. And in that procedure, you use a mesh, and you've just discussed several different mesh products that are sold by different companies that you think are all suitable and appropriate for mesh implantation; is that fair?

A. Yes, there are different companies that have suitable meshes.

Q. And those meshes have slight differences, as we have discussed, based on their knitting and various design properties, correct?

A. Correct.

Page 238

Q. Doctor, there's been a -- we've discussed this somewhat, but there's been a various selection of different materials that have been used as implants to treat incontinence through the history of treatment for incontinence; is that correct?
A. Correct.
Q. And some of those materials were Gore-Tex or Mersilene or polyester, correct?
A. Correct, yes.
Q. And each one of the different products had different results; isn't that correct?
A. Correct.
Q. And a lot of the variation is driven by, one, the material that goes into making the product; is that correct?
A. One of the components is the material, yes.
Q. And some other variation could be by the way that material is made into the mesh implant, the way it's designed;

Page 239

is that correct?
A. The way it's knitted or weaved is what you're getting at.
Q. Sure.
A. Okay.
Q. And that will affect various properties, such as weight, density, flexibility, tensile strength, correct?
A. Well, I think the density of the fiber stays the same depending on what fiber you use, but the weight of the mesh, sure.
Q. The ultimate mesh will have different characteristics based on the design of the mesh, correct?
A. Correct.
Q. So, there is some variation in different mesh products even though they all started at polypropylene; is that correct?
A. That's correct. There are different additives that I'm aware of that companies put in in their polypropylene that are proprietary.

Page 240

Q. And those different properties and additives and designs actually have implications at the ultimate level for the patient; is that correct?
MR. ROSENBLATT: Object to form.
A. They may. I don't know if we're going to be able to drill down and be specific as to which product has, or which additive, quote/unquote, has the specific complication.
Q. That's why it would be important to look at safety and efficacy information specific to the specific product; isn't that correct?
MR. ROSENBLATT: Object to form.
BY MR. BENTLEY:
Q. You wouldn't want to establish the safety of one product based off of some other polypropylene product that has a different design, would you?
A. Well, I think there are some assumptions that you can make and, at that point in time, of how similar or dissimilar the meshes are. If you're

Page 241

going to show me a mesh and that's a .2 millimeter pore size and say use this for stress urinary incontinence, I wouldn't use that.
Q. But if you had two products, both made of polypropylene, similar width, thickness, with different pore geometry, you'd want to look at the safety information for the specific one you're using; is that fair?
A. It's one of the components that I would look at. It's not the only component about the product or device that I would look at and take into consideration.
Q. Was it important to you that Ulmsten found no defect in healing in his initial study?
A. Can you tell me what you're referring to?
Q. I'm sorry.
You know who Professor Ulmsten is, don't you?
A. Yes.

Page 242

Q. Who is Professor Ulmsten?
A. He was one of the, quote/unquote, fathers of the TVT procedure.
Q. And you cite to him in your report as Ulmsten developed the TVT, correct?
A. Yes.
Q. And Ulmsten did the first study on TVT using Ethicon's Prolene mesh; is that correct?
A. Yeah.
Can you tell me what page you're on there?
Q. On page 27 of your report, at the bottom you begin discussing the Ulmsten prototype.
Do you see that?
A. Yes, I do.
Q. And then the next sentence you're discussing the Falconer/Ulmsten '96 studies.
Do you see that?
A. Yes, I do.

Page 243

Q. And then on the next page, a subsequent study for a publication you say: Ulmsten '96 discussed the improvements in finding no defect in healing."
Do you see that?
A. Yes, I do. In 1996 he did write that.
Q. And that's the first study where he's using Prolene for TVT; is that correct?
A. That I'm aware of, that's correct.
Q. And you state that he found no defect in healing, correct?
A. Correct.
Q. Would it concern you if he misrepresented that result?
A. At this point in time, it doesn't concern me because the proven safety and efficacy and multiple Level I studies have shown that the device is safe and efficacious.
Q. So just so I'm clear, your

Page 244

testimony for the jury that you're unconcerned that Ulmsten --
MR. BENTLEY: Strike that.
Q. If evidence shows that Ulmsten, the creator of this device and the initial publication regarding this, if he misrepresented that there was no defect in healing, you're not concerned about that?
MR. ROSENBLATT: Object to form; mischaracterization; lack of foundation.
A. So, can you repeat the question?
Q. Sure.
At trial, do you intend to tell the jury that you're not concerned that Ulmsten may have misrepresented --
MR. BENTLEY: Strike that.
Q. If you're presented with evidence at trial, do you intend to tell the jury that you're not concerned if Ulmsten misrepresented the fact that TVT in the initial study did indeed have a healing defect? Does that not concern you?

Page 245

MR. ROSENBLATT: Same objection.
A. I would be concerned about anybody who publishes a research article if they misrepresent what they found.
I'm going to assume that he didn't misrepresent it.
Q. Okay.
A. But if you tell me now that there was an exposure rate of 2 percent, I'll -- I believe it and I'm not going to base the credibility of Ulmsten on what the information that we have today.
Q. Would it concern you if information showed that there was a defect in healing and that Ulmsten had a pay-for-play agreement regarding the product?
MR. ROSENBLATT: Objection; lack of foundation and mischaracterization.
BY MR. BENTLEY:
Q. You can answer.
A. I understand that Ulmsten was paid --

Page 246

MR. ROSENBLATT: Argumentative.
A. I understand that Ulmsten was paid for his -- the product, and I understand that he did get money for it.
What I do think is if someone has product information or comes up with a device, they should be able to be compensated with an industry if it's their intellectual property that's going to be used.
Q. My question was just do you intend to tell the jury that that doesn't concern you if he misrepresented data that he was getting paid to present it favorably?
MR. ROSENBLATT: Object to form.
Greg, let's pull it out and look at it if you want to ask him about it.
MR. BENTLEY: I'm just talking about the hypothetical.
We know what the data shows.
MR. ROSENBLATT: Well, let's pull it out and look at the data so he can give you a better answer.

Page 247

MR. BENTLEY: I don't care about that.
BY MR. BENTLEY:
Q. The hypothetical, just go with this assumption. Assuming the data showed that Ulmsten had healing defect in his initial study and he was getting paid based on whether or not he had no defects, if he misrepresented that data, would that concern you? My question is only would that concern you?
MR. ROSENBLATT: Object to form; lack of foundation.
A. It may concern me on his character, but it's not going to change the way I feel and my opinions on midurethral slings today.
Q. Doctor, what would you consider, or how would you describe your medical expertise or specialty?
A. I don't understand. What do you mean?
Q. How do you describe what you do?
A. To people, let's say to a layman?
Q. To me maybe.
A. Yeah, no problem.
So, most commonly what I say to people who ask me what I do is I do urogynecological, that's female pelvic reconstructive medicine. The most common things that we deal with would be pelvic organ prolapse, which is when something is falling down or out of the vagina, and the second most common thing that we will manage and treat is stress urinary incontinence -- is urinary incontinence, and then they may ask me what urinary incontinence is, and I may explain to them the difference between stress and urge incontinence.
Q. So you would classify yourself as a urogynecologist, right?
A. I would classify myself as a female pelvic medicine reconstructive surgeon because that's what the board certification is, but it's easier to say urogynecologist, for sure.

Page 248

Page 249

Q. And that's of course different than just a gynecologist, correct?
A. That's correct.
Q. And is that different from, in your interpretation, is that different from a urologist?
A. From a general urologist, yes.
Q. And each of those specialties have, I presume, different certifications?
A. Yes. So, both urology and obstetrics and gynecology have general board certification, and they also have subspecialty board certification.
Q. And they have different training, I presume; is that correct?
A. Well, the training for the subspecialty for female pelvic medicine is supposed to be, at this point in time, a little more, what's the word I'm looking for, structured, for lack of better terms right now. Standardized, structured.
Q. Fine.
Is there different accreditation, I would presume, for the

Page 250

different subspecialties?
A. So, there's a combined board for the female pelvic medicine and reconstructive surgery certification, and I'm not exactly sure on how the credentialing works on the urology side. They get their female pelvic medicine and reconstructive surgery from the urology side, but it's sort of a combined board between OB-GYN and urology. There are three people from each specialty on that board.
Q. And there's urology-focused journals, correct?
A. Yes, there are.
Q. And there's gynecology-focused journals, correct?
A. Yes, there are.
Q. And there's actually, I think, reconstructive pelvic medicine-focused journals, correct?
A. Yes.
Q. And each of those journals brings a different perspective to the

Page 251

table; is that fair?
A. Yes, they do.
Q. It's a little different knowledge and practice in each one of those?
A. Theoretically. I mean, yes, theoretically there may be different ways of looking at things, although in the female pelvic medicine side, there has been a lot of work in the last ten years to try to more standardize that, whether it's coming from the urology side or whether it's coming from the GYN side.
Q. In the last ten years, the urology and gynecology have kind of converged into female pelvic medicine reconstructive surgery?
A. Right.
Q. And prior to them converging in the middle, urologists might have preferred one procedure for the same indication as compared to gynecologists were doing a different procedure for that same indication?

Page 252

A. Yeah, and I think I actually wrote about that in my report. In the late '90s, urologists were more commonly doing pubovaginal slings for urinary incontinence and that's where their training came from. And they were almost suggesting, and some urologists were suggesting that everyone if they were getting an anti-incontinence procedure, a pubovaginal sling should be the primary procedure that you're performing.
Gynecologists, as a general rule, were more commonly performing Burch procedures.
Q. You were doing Burch procedures in that time period predominantly?
A. So, that was one of the things that I got lucky with, I think, in terms of my training. That yes, we did abdominal procedures, but we also did pubovaginal sling procedures. We also did bone anchored procedures, not that bone anchors are the way to go today, but I did have -- and we did urethrolysis. So I

Page 253

felt I got extensive training on both sides of the spectrum, and I felt that I was lucky because of that.
Q. You don't have any criticism of the urologists for preferring the pubovaginal sling, do you?
A. No, and I understand where that came from.
Q. It was based upon their knowledge and training and they thought that was the better procedure?
A. Yeah, they're entitled.
Q. And the other side, you don't have any criticism of the gynecologists who thought, based on their training and knowledge, the Burch was better?
MR. ROSENBLATT: Object to form.
Are you talking about then or now?
MR. BENTLEY: Then.
MR. ROSENBLATT: Okay.
BY MR. BENTLEY:
Q. You discussed in your report that in the late '90s when urology and

Page 254

gynecology were separate before they converged that there was different preferences in how to treat incontinence, that the urologists preferred to do the pubovaginal sling, correct?
A. Correct.
Q. And back then, the gynecologists --
A. I would say most urologists, not all.
Q. Of course.
And conversely, gynecologists preferred to do the open Burch procedure, correct?
A. Correct.
Q. And you don't have any criticism of the gynecologists' preference for doing the Burch back then, correct?
A. No. I think it was the procedure that you can do back then.
Q. And that's because they had training and knowledge that indicates to them that this was the more appropriate procedure for them to recommend in the

Page 255

majority of the cases, and you're not critical of that, are you?
A. I'm not going to criticize what they picked. I think that most people back then did the procedure that they were comfortable and trained with. If they didn't know how to do a pubovaginal sling, I don't think they were going to offer it.
Q. Because they had a different understanding and a different knowledge base and that led them to a different preference back then; isn't that correct?
A. Yes, that led them to, based on their training and education, led them to the preference of one over the other.
Q. Which may have been different for urologists versus gynecologists, correct?
A. Yeah, I don't recall -- I'm not -- I don't recall what the specific training for urologists were back then. I can tell you what urogynecologists and gynecologists were doing, but as a general rule, we tended to lean more towards a

Page 256

Burch procedure for a primary repair as opposed to an autologous sling procedure.
Q. Doctor, in your report, you mention that every patient is slightly different, and that goes without saying, right?
A. Correct.
Q. And every surgeon is different how they would like to do something, correct?
A. Slightly, yes.
Q. And a surgeon's differing preference on how to do it is based in part on his or her experience, correct?
A. Correct, and it may be based on their height, their weight.
I don't know what to tell you.
Q. And based upon their knowledge based on what journals they're reading?
A. Correct.
Q. And what training programs they're going to, or CMEs, correct?
A. Correct.
Q. And everyone's slightly

Page 257

differently positioned, correct?
A. You're talking about patients or surgeon?
Q. Well, actually both; isn't that correct?
A. Yeah, one surgeon may prefer to position with one type of stirrups and another surgeon may prefer to position with another set of stirrups. One surgeon may want more flexation of the hips, one person may want less flexation of the hips.
Q. Doctor, you're a member of the ACOG and AUGS, correct?
A. Correct.
Q. And ACOG and AUGS put out practice bulletins, correct?
A. Yes, they do.
Q. And you rely upon those, right?
A. It's one of the things I rely on.
Q. You cite to them in your reliance materials, right?
A. That's correct.

Page 258

Q. Would you consider them important evidence?
A. I think those are some things you should take into consideration when you're doing these procedures, yes.
Q. What level of evidence would you classify those position statements as?
A. I would classify those position statements as guidelines as opposed to a, quote/unquote, level of evidence.
Q. Got you.
Do you have an opinion as to whether TVT has rough edges or smooth edges?
MR. ROSENBLATT: Object to form.
A. I don't have an opinion if one is rough or smooth in particular.
Q. If you want to look on page --
A. I have an opinion that the laser-cut TVT has a more of a rounded type of edge and the TVT mechanical may have a, quote/unquote, slightly pointier edge, and how that feels to an individual surgeon may be different.

Page 259

Clinically, I don't think that it makes a difference if you have -- that I've seen in my patients or that I've been reported if there's a difference between those two particular type of edges.
Q. So, laser-cut mesh is going to have more of a smooth sealed edge; is that correct?
A. So, if you're touching one of the edges.
Q. Right.
A. It's, yeah, it's smoother.
Q. And machine-cut's going to have a little bit rougher edge without the sealed laser-cut process?
A. I mean, I don't know if I describe it as a rougher edge all the time, but I think that it may have a different type of a feel to it, yeah.
Q. And the feel or roughness of the edge, that's a product of the cutting process; isn't that correct?
A. Yeah, the edges are a product of the cutting. How the edges turn out are a

Page 260

product of the cutting process.
Q. And that's part of the design of the mesh, whether or not you design to be laser-cut or machine-cut, right?
A. I don't think it's the way of the design of the mesh. I think it's the way that you're cutting the mesh.
Q. Which is part of the design of the manufacturer, correct?
A. Okay.
Q. I mean, if the design specifications call for laser-cut, that's part of the design?
A. Correct.
Q. And conversely, if the design calls for a machine-cut, that's part of the design, right?
A. Correct.
Q. And the resulting rough or not as smooth edges is inherently part of the design, right?
A. The edges are inherently part of the design, yes.
Q. Okay. On page 28 of your

Page 261

report, you have a paragraph that starts "A standard weight mesh."
Do you see that?
A. Yes.
Q. And the second sentence you're discussing the Prien-Larsen 2016 study and you state that: "They recently published a prospective study comparing 100 grams per meter squared with low stiffness and rough edges similar to TVT."
Do you see that?
A. Correct. That's how they described it in the paper.
Q. Well, you're saying that that's similar to TVT, and there you're talking about machine-cut; is that correct?
A. Yeah.
Can you pull out the paper, do you mind?
Q. I'm just talking about your report. There's not a direct quote in that sentence, is there?
A. No, there is not.
Q. So you're just saying that the

Page 262

rough edges are like the machine-cut TVT, right?
A. I said they're similar to the TVT.
Q. As we discussed, that would be the machine-cut TVT as opposed to the laser-cut?
A. That's correct.
Q. Doctor, you make a couple of statements in your report talking about your opinion as to what is commonly.
You're aware of that, right?
A. That I used the word "commonly"?
Q. Yes.
A. I used it in my report. I don't know how many times I used it, but it's in there.
Q. On page 23 of your report, you have a paragraph that starts with "The TVT procedure has been shown."
Do you see that at the top?
A. Yes.
Q. And, I apologize, the paragraph starts on page 22 and ends on 23.

Page 263

A. Okay.
Q. In that sentence that carries over from 22 to 23 you state: "Despite the high success rate of TVT, there are failures as with any procedure, and surgeons are acutely aware that certain types of patients may have higher success rates than others."
My question is is there a difference in your report when you use a phrase such as "acutely aware" versus "commonly aware" or "commonly known"? How are you choosing those?
A. I probably didn't want to use "commonly" so many times. That's what I learned in writing class as, well, you're not supposed to use the same word twice in a paragraph. So that's probably why I picked that word "acutely."
Q. And when you're opining as to what surgeons are acutely aware of, that's based on your experience generally; is that fair?
A. That's based on the literature

Page 264

that's published, as well as my experience.
Q. That's based upon the literature that you've reviewed and your experience, correct?
A. Correct.
Q. Because you really -- we have no way of knowing what every surgeon in the U.S. and every geographic region and every specialty reviews, right?
MR. ROSENBLATT: Object to form.
A. All I know is what every surgeon and what every resident, and forget about every resident and medical student should be trained on. That's what I know.
Q. Right.
A. Would I know what everyone else is thinking? Absolutely not.
Q. And those can be, unfortunately, slightly different; is that fair?
A. I will agree with you.
Q. Some surgeons may not be acutely aware of all of the complications and their frequency?

Page 265

A. So, in my opinion, if you're doing a procedure, you should be aware of the complications.
Q. I give you that. They should be.
A. Okay.
Q. But you would give me that they may not actually be aware, unfortunately?
A. Once again, I can't opine on what people know or don't know. I can only opine on what we're supposed to be taught.
Q. Appreciate that.
And then on page 35, you have a paragraph in the middle that begins with "The surgical risks."
A. Yes.
Q. And you state: "The surgical risks and complications for stress incontinence procedures are commonly known and not unique to TVT."
Is that correct?
A. That is correct, that's what's written.

Page 266

Q. I think I understand now, your opinion there is based upon what you think they should know; is that correct?
A. My opinion is based on what we are required to teach and what I teach and what I know my fellow urogynecologists teach upon discussion with them.
Q. Right. And that being said, we still don't know exactly what every surgeon knows, unfortunately?
MR. ROSENBLATT: Object to form; asked and answered.
A. I can't opine on what people know and what they don't know.
Q. And there's no studies --
A. There's no right answer for this question.
Q. There's no studies polling the knowledge of surgeons as to their knowledge of complications associated with TVT products to treat incontinence, right?
A. Say that again.
Q. That was a great question, I'm just going to read it back to you.

Page 267

There's no studies polling the knowledge of all surgeons as to their knowledge of complications associated with the TVT products to treat incontinence, right?
A. I don't think there are any studies. I'm not aware of any studies that will attest to what doctor knows about incontinence and what they don't know about incontinence.
I will tell you that there's a certifying exam that if they want to be a female pelvic medicine doctor will give them certification in their knowledge of the pelvic floor, for instance.
And there's a certifying exam for the specialty as well in OB-GYN which they have to pass if they want to call themselves a board certified physician.
Q. When did the FPMS --
A. FPMRS.
Q. FPMRS exam, when did that accreditation come out?
A. The first time that exam was

Page 268

given was in 2013.
Q. And of course the slings have been implanted since at least 1998, right?
A. Yes.
Q. And on page 41, you have one paragraph that begins "The possibility."
Are you with me?
A. Yes.
Q. And you say: "The possibility of developing chronic pain and dyspareunia are inherent to vaginal surgery independently and do not need to be explicitly mentioned in an IFU as every implanting surgeon would have possessed this knowledge through their education, training and practice."
And to maybe make this more clear, should that state that implanting surgeons should have possessed this knowledge, in your experience, because we have no basis of knowing what they knew, right?
MR. ROSENBLATT: Object to form.
A. So, my understanding on the

Page 269

educational process, and we have it -- I'm going to say specific to OB-GYN, we can talk about urology if you'd like, but specific to OB-GYN, every single physician when they do vaginal surgery is taught that chronic pelvic pain and dyspareunia can happen. It can happen after a vaginal delivery and an episiotomy repair. It can happen after hysterectomy. These are complications that should have been known by everyone. I can't imagine -- no one's going through an OB-GYN residency without doing a hysterectomy and no one's going through an OB-GYN residency without doing an episiotomy.
Q. You're talking about just the possibility of these complications occurring, right?
A. Correct.
Q. And let's talk about the frequency of these complications happening, okay. We're limiting it to frequency, not possibility.
Are you with me?

Page 270

A. Yes.
Q. Would you agree with me that not everybody knows, necessarily, the true, accurate frequency with which these complications occur after the TVT implantation?
A. I can go based on the published literature of what the frequency and the complications are.
Q. Right.
A. Do we have a registry of every single person who got a TVT in the world? No, we don't.
Q. All right. So, based off your review of the literature, what's your opinion as to the true rate of erosion after TVT implantation?
A. On my review of the literature, it's approximately 2 percent.
Q. And you've reviewed an extensive amount of literature, right?
A. Yes, I have.
Q. And you understand that some doctors haven't reviewed as much

Page 271

literature as you have. Would you agree with that?
A. I would agree that not every doctor is reviewing as much literature in this that I have, but the exposure rate is something that is -- it's the most common complication, almost, that we see when we're talking about real complications as opposed to like a urinary tract infection, that anyone implanting that, anyone implanting a foreign body would know that exposure is a possibility.
Q. And I'm not trying to talk about possibility. I'll give you that.
A. Okay.
Q. I'm saying that you know there's physicians out there that haven't had the opportunity to review this amount of extensive literature that you have.
You agree with that, right?
A. I agree with that, yes.
Q. I mean, there's hundreds of articles probably in here?
A. It's a lot.

Page 272

Q. And not every physician has time to do that, unfortunately, right?
A. That is correct.
Q. And so it's possible that there's doctors out there that don't have the same high level of knowledge of the literature regarding TVT complications as you do, right?
A. I think they would have the basic knowledge on the complications of a TVT.
Q. But they don't have your explicit extensive knowledge regarding the frequency that's in the literature?
A. I don't -- they may not have done the same amount of literature searches, but I can't comment if they know the frequency or not. That's pretty much out there at 2 percent.
Q. You just don't know what they know, right?
MR. ROSENBLATT: Object to form.
A. Once again, I can't opine on what they know. I can opine on what they

Page 273

should know, in my opinion.
Q. Doctor, what's your understanding of whether or not --
MR. BENTLEY: Let me rephrase that.
Q. What's your appreciation of when a company such as Ethicon should introduce changes to one of its marketed products? Generally what's your standard?
MR. ROSENBLATT: Object to form.
Are you talking about the design?
BY MR. BENTLEY:
Q. Do you understand my question?
A. No.
Q. If you want to turn to page 28. You're talking about product design and you start out "Due to the large volume."
Do you see that?
A. Yes.
Q. And you've testified that you've consulted on product design with companies, right?
A. Correct.

Page 274

Q. And you have a sentence towards the end you say: "Therefore, it was appropriate for Ethicon to not introduce changes to the mesh too rapidly."
Do you see that?
A. I see that.
Q. And you've consulted with companies on what changes to make to their products; is that correct?
A. That's correct.
Q. And my question simply is what is your standard for whether or not it's appropriate to introduce changes? What's your basis or your standard that you're reaching this opinion?
A. I don't think there's one specific standard.
I think it depends on what change you're making, what modification you're making, and when in the time frame of the product where it was would affect when you should make your changes.
Q. And it sounds like you're applying maybe a common sense standard

Page 275

based on your experience as a practicing surgeon.
Is that a fair summation of it?
MR. ROSENBLATT: Object to form.
A. That's the way -- you asked me what my standard was. That's what mine is.
Q. I'm just trying to figure out your basis for that.
A. Yeah, that's okay.
Q. You're not citing or referring to any federal regulation there; is that right?
A. Yeah, I think a company can -- is allowed to make changes when they want. They just need to apply to the rules and regulations.
MR. BENTLEY: Off the record.
(Luncheon recess taken from 1:22 p.m. to 2:13 p.m.)

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Page 276

A F T E R N O O N S E S S I O N
BY MR. BENTLEY:
Q. Doctor, we're back from a quick lunch.
Are you ready to go?
A. Yes, I'm ready.
Q. What suture material do you use, generally?
A. For what type of procedure?
Q. For Burch procedure.
A. 2-0 Gore-Tex are my suspension sutures, but then I'll use other sutures to close fascia, close skin.
Q. We previously discussed that in the late '90s, doctors were trying to use Gore-Tex material for slings to treat incontinence.
Do you remember that?
A. Yes, I do.
Q. And those slings had poor results; is that correct?
A. Yes, the longer length slings.
Q. So, just because you use a Gore-Tex suture material today doesn't

Page 277

necessarily establish the safety and efficacy of using Gore-Tex for a sling to treat incontinence; is that correct?
A. Yeah, they're different materials that I'm using. But they're also using them for different purposes.
Q. Doctor, before we broke, we were discussing the inflammatory response to TVT and TVT-Exact once it's implanted.
Do you remember that?
A. Yes, I do.
Q. And I believe you testified that there's a chronic inflammatory response and a transient inflammatory response?
A. There's an acute and a chronic one, is what I think I testified to.
Q. You understand that the mesh once implanted has a chronic inflammation response that continues indefinitely?
A. I think the fibers in the mesh induce a chronic inflammatory response.
Q. And that response is indefinite while the mesh is implanted, correct?
A. It's ongoing. Clinically we

Page 278

don't see an evidence, like evidence of an inflammatory process going on in terms of infection -- in terms of infectious areas, fevers, erythema around those areas, but yes, there is a long-term chronic inflammatory response that occurs.

Q. So you wouldn't tell your patients that TVT inflammatory reaction is transient, would you?

MR. ROSENBLATT: Object to form.

MR. BENTLEY: Let me rephrase it.

BY MR. BENTLEY:

Q. When you consent your patients, you provide them truthful and accurate information, right?

A. I try to.

Q. Right. And if you were discussing the inflammatory reaction that can happen once the TVT mesh is implanted, you wouldn't describe it as transient, would you?

A. Well, I wouldn't describe that the chronic inflammatory reaction is

Page 279

clinically evident either.

Q. You would tell them there's a chronic reaction --

MR. BENTLEY: Strike that.

Q. You would tell your patients there's a chronic inflammatory response maybe in addition to the acute transient response you were talking about?

A. No, I would tell my patients that this is a permanent implant. Whether or not they're going into inflammatory responses would depend on their questioning and what they -- how in-depth they want to go on that.

Q. And in that discussion, if it did go into the topics of inflammation, you wouldn't describe it to your patients as transient?

A. What I would describe is that there's a chronic inflammatory process that occurs with any type of implant that is placed in the human body.

Q. And are you aware that the IFU for TVT states that the inflammatory

Page 280

reaction is transient?

A. I'm aware of that. And my understanding of that is that of the acute inflammatory reaction that occurs whenever you have an incision in surgery.

Q. And you understand that that explanation is not provided in the IFU though, right?

A. It's not explicitly written in the IFU.

Q. Would you want to maybe provide that better explanation in the IFU so it's more clearly conveyed that there is indeed a chronic inflammation response?

A. Once again, I would put in the IFU what federal regulations require me to put in.

Q. And you don't want to put misleading information in the IFU, right?

A. Once again, I would put in the what the federal regulations require.

Q. You can agree with me that the federal regulations don't permit misleading information, right?

Page 281

A. I would agree with you that federal regulations don't want misrepresentation of what's going on.

Q. So, to more clearly portray what happens with the inflammatory response in the body, if you're going to discuss the inflammatory response in the IFU, you would want to say that it's chronic, correct?

MR. ROSENBLATT: Object to form.

A. No, I wouldn't.

I think that's pertaining to the surgical procedure, what's mentioned in the IFU. Any type of implant is going to cause a chronic inflammatory reaction. It's commonly known.

So why would I need to include that in my IFU?

Q. Well, why would you say it's transient in the IFU?

A. 'Cause I think they were trying to explain to physicians about the process of when you're putting it in and what happens when it's placed in.

Page 282

The IFU is never meant for patients. It's meant for physicians.
Q. And you don't think that it's more balanced to discuss the chronic inflammatory response in addition to the transient inflammatory response if you're going to discuss the inflammatory response in the IFU?
A. Well, I think the acute inflammatory response is clinically evident. The patient may feel incisional pain and may feel cramping pain. The chronic inflammatory response is not clinically evident.
Q. So you don't think you should put that in the IFU with the other discussion to make it fair and balanced?
A. Once again, it's not my opinion that counts in the IFU. It's what the federal regulations and guidelines require in the IFU.
Q. So, your opinion, Doctor, generally your opinion is that the TVT is safe and effective; is that correct?

Page 283

A. That is correct.
Q. And what do you consider as a good efficacy rate for a product that's implanted permanently to treat incontinence?
A. Well, I wish we could get to a hundred percent, but I know that's not realistic, and I think a product that gives us about the 80 to 85 percent success rate, and if we can get a little higher to closer to 90 percent, and some studies have shown that, would be a good product.
Q. Regarding a complication rate, what would you consider an acceptable reoperation rate for a permanent implant that's used to treat incontinence?
A. Well, that's going to depend on the patient, as well as what the other procedures that I have available to me are.
So, sometimes a 2 percent may be acceptable, sometimes a 4 percent, sometimes an 8 percent be acceptable.

Page 284

So I'm going to try to go to fall back on the clinical literature to see what the acceptable reoperation rates or what the reoperation rates are with my procedures now to try to come to a determination of what it should be with a TVT or any kind of midurethral sling.
Q. I need to nail this down, Doctor.
Based on your review of the literature, and we need to know what you're going to tell the jury. It's important. And based on your extensive review of the literature and 60 pages of reports and countless articles, have you come to a conclusion of what an acceptable rate is for a reoperation for a permanently implantable device used to treat incontinence?
A. So, I will base it on some of the studies, the Canadian study that was out there. I think somewhere between a 3 to 4 percent reoperation rates would be acceptable.

Page 285

Q. So something above that would be unacceptable, using that standard?
MR. ROSENBLATT: Object to form.
A. I don't know if it would be unacceptable. It's going to depend on the patient. But if you're talking in thousands of women, I think that those numbers would be acceptable.
Q. Okay. And similarly, what is your opinion based on your review of the literature and your experience of an acceptable rate of erosion for a permanently implantable mesh like the TVT and TVT-Exact used to treat incontinence?
A. I think the 2 percent erosion rate that has been reported, the approximate 2 percent erosion rate that's been reported on TVT is acceptable.
Q. So using that standard, something above 2 percent would be unacceptable, in your opinion?
A. Once again, it depends how far above that 2 percent is there. So if you're going to tell me 2.1 percent, I

Page 286

probably will say no, it doesn't matter. If you're going to tell me 10 percent, then I would consider it based on the standard deviation and the statistics that are provided to me.

Q. And what is your definition of what an acceptable rate of exposure is for a permanently implantable device used to treat stress urinary incontinence like TVT and TVT-Exact?

A. Well, I think you base the standard rate based on the gold standard right now.

So my acceptable rate, if I had a product that was higher than the TVT or the midurethral sling, I would have to fall back and say the TVT is the standard.

Q. I need to know what your opinion is as to what you think the exposure rate is, and so I need to know what you think the acceptable rate is.

So my question is, Doctor, based on your review of the literature and your experience, what is an acceptable rate of

Page 287

exposure for a permanently implantable device used to treat stress urinary incontinence like TVT and TVT-Exact?

A. In 2017 --

MR. ROSENBLATT: Object to form.

Q. You can answer.

A. In 2017, I think a 2 percent exposure rate is acceptable.

Q. And just to clarify, your 2 percent exposure rate, is that you're talking about external outside the body exposure?

A. Yes, I'm talking about an exposure rate. I'm not talking about total reoperation rate.

Q. And your definition of an acceptable erosion rate, that was talking about internal organ perforation type erosion; is that correct?

A. There is -- yes, there is an acceptable rate. That is even lower than, I would say, what's the -- in my report, we do have a number of the acceptable rate.

Page 288

Can we find what that was?

Q. Well, that's the problem is there's a number of studies cited in here and there's no analysis from you. I don't know what your opinion is.

A. Okay.

Q. What's your opinion based on the literature and your experience of an acceptable rate of erosion for a permanently implantable device like the TVT and TVT-Exact using your definition of erosion that we had previously discussed?

A. I would say it's .1 percent or less would be acceptable.

Q. And based on your review of the literature as discussed in your report and your experience, what is your definition of an acceptable rate of de novo dyspareunia after implantation of a permanent device used to treat stress urinary incontinence like the TVT and TVT-Exact?

MR. ROSENBLATT: Object to form.

When you're saying "acceptable,"

Page 289

do you mean what's commonly reported in the literature or just his personal?

MR. BENTLEY: His report says that it's 1 percent and it's 5 percent and it's 15 percent. But he says it's safe and based off of 50 different numbers. I have no idea still exactly what he thinks the rates are.

MR. ROSENBLATT: I just can't figure out if you're asking about what he personally finds acceptable or what's generally reported in the literature.

MR. BENTLEY: That's why I'm saying based off his experience, what is his rate.

MR. ROSENBLATT: Okay.

MR. BENTLEY: I'm just trying to figure out what he thinks the rate is. I don't know how else to.

MR. ROSENBLATT: Got it.

A. I understand.

I can tell you what I think the

Page 290

rate is in my hands for retropubic slings, and what -- and with the retropubic sling, I think the incidence of chronic pain and dyspareunia is low. An acceptable rate for me personally may be anywhere from, for a retropubic sling anywhere between 2, 3, 4 percent.

Q. For de novo dyspareunia, is your testimony that an acceptable rate of de novo dyspareunia for an implantable permanent device to treat stress urinary incontinence, your opinion is an acceptable rate of de novo dyspareunia is 2 to 4 percent?

A. I think it should be lower than that, thinking of it that way. With the retropubic sling, I don't think we see it more than 1 to 2 percent to the time in my personal experience. With some of the other slings we may see it more.

And it's also going to depend on the patient population that you're treating, if you're treating post-menopausal or pre-menopausal patient

Page 291

population.

It's also going to depend on if there's pre-existing dyspareunia as well and what are the other factors that are associated with it.

It's hard to pin down an exact number, and that's why a lot of these studies don't give you that kind of exact number. It's hard to get to.

Q. Your answer, I think you said, was 1 to 2 percent; is that correct?

A. Personally, if my patients had a higher than 1 to 2 percent rate and that's what I was finding out, I would look to see what is going on.

Q. You understand that you're in this litigation to give general causation opinions about the device?

A. Correct.

Q. And you're being presented to testify to the jury as to what your opinions are regarding the complications to TVT and TVT-Exact, right?

A. My understanding is that I'm

Page 292

testifying of whether or not the complication rates are higher than with what was commonly known out there and what the rates are as opposed to the absolute rates of the surgical procedures.

Q. Do you have an acceptable -- Doctor, based on your literature review as discussed in the TVT and TVT-Exact report and based upon your clinical experience, what is your opinion as to what is an acceptable rate of chronic pain following the implantation of a permanent medical device, such as TVT and TVT-Exact, to treat stress urinary incontinence?

A. So, for this type of procedure, I would like to see it around the 1 percent range, and I think that's what's reported in the literature of chronic pain at around the 1 percent range with the retropubic sling. And sexual dysfunction is probably reported at 0 to 1 percent, but I'm not going to say there's 0 for anything.

Q. Okay. So, based off of the

Page 293

rates we've just discussed, you would agree that there's a wide range of complication rates discussed in your report for the TVT and TVT-Exact; is that correct?

A. Yeah, that's correct. Different studies reported differently. So once again --

Q. And some studies may be above and some may be below your acceptable rates; is that fair?

A. That's fair.

Q. And based on your review of the literature, these are the rates that you determined are safe and acceptable; is that correct?

A. I think this is what occurs in the literature.

Q. And you didn't do any type of systemic analysis to combine all of those figures and run a meta-analysis to tell me what the combination of all of that data spits out as the actual rate, right?

A. No, I didn't. I can base it on

Page 294

the clinical literature and my personal experience seeing patients back for follow-up, seeing them postsurgically, seeing them in the years after, seeing them in social situations, seeing them in the hospital, and from my referring physicians telling me how these patients are doing, as well as colleagues who would tell me if I -- if they had saw a patient of mine with one of these complications.

Q. And is that the extent of the basis?

A. The clinical -- the literature and my clinical experience, yes.

Q. Doctor, you would agree that different slings manufactured by different companies have different efficacy rates and complication rates, wouldn't you?

A. Different slings can have different efficacy rates and complication rates, yes.

Q. And one of the things you're going to look at is ultimately the quality of life after the implant procedure for

Page 295

the patient?

A. That's one of the things that we looked at for outcomes is quality of life, correct.

Q. That's an important measure?

A. It is one of the important measures.

Q. And you've, in fact, studied whether there is a difference between different slings made by different companies on patient quality of life, right?

A. There are studies out there comparing slings, yes.

Q. You have actually done those studies, right?

A. I did those studies.

I'm trying to recall which one in particular you're talking about. So I can get to my CV and we'll take a look.

Q. I'm going to hand you what is being marked as 26.

(Exhibit Winkler 26, Shalom article, was marked for

Page 296

identification, as of this date.)

BY MR. BENTLEY:

Q. This is a study by you from 2011 that was published in the International Journal of Gynecology and Obstetrics, correct?

A. Correct.

Q. And the title of the study is "Comparison of quality-of-life changes in patients with stress urinary incontinence after midurethral sling placement."

Correct?

A. Correct.

Q. And in this study, you evaluated the Ethicon Retropubic TVT versus the AMS SPARC; is that correct?

A. Correct. This particular data was from a patient population from Dr. Klapper. I did work on the study, but it was not patients that I operated on.

Q. And your name's on the study, right?

A. Yeah. I participated in the study. There's no question about it.

Page 297

Q. It's a good study in a reputable journal, right?

A. I'm just telling you I didn't operate on these patients.

Q. And this study found that there was a difference in quality of life between the AMS sling and the Ethicon sling, right?

A. Let me just read it over again. It's been a while since I've looked at this study.

Well, the UDS scores for the suprapubic versus transvaginal were the same. Postoperative patients underwent a super -- yes, so the UDI-6 scores for the transvaginal procedure were lower in this study.

Q. And in the last page, actually the conclusion that you put, you and the other authors on this article conclude: "However, improvements in UDI-6 quality of life scores was significantly better in the suprapubic group."

And that's the AMS device,

Page 298

right?
A. That's the AMS device, the SPARC, yes.
Q. In this same column at the top, you and the authors hypothesized that the difference in diameter of the trocars may have affected the quality of life; is that correct?
A. Can you show me where that is?
Q. Sure.
At the top you put: "There are subtle differences between suprapubic and the transvaginal instruments used for" --
A. Yes, so that was a hypothesis back in 2011. Today I would base my opinions and conclusions on Cochrane reviews, which is higher level evidence than my paper back then, stating that the transvaginal approach is better. It has a slightly higher objective rate than the suprapubic approach. And clinically, my patient population, I did see good results with the transvaginal approach, and that's why I continued with it.

Page 299

Q. And in this published article though, you note that the quality of life was improved in the AMS device, right?
A. Correct.
Q. And one of the differences with the AMS device is it has that 3 millimeter trocar compared to the Ethicon TVT which is 5 millimeter trocar, right?
A. In 2011 I had already converted away from the Ethicon larger trocar.
Q. And in this article you found that there was a difference in quality of life, right?
A. Correct.
Q. And you hypothesized that maybe it was due to the diameter in trocar, right?
A. There were subtle differences, so we said that that may be one of the reasons, correct.
Q. And you explain that the differences in diameter may result in a more limited dissection and a resulting tissue injury or inflammation.

Page 300

Do you see that? It's in that top right paragraph.
A. Yes, I do. And that would be on acute inflammation and acute tissue injury.
Q. So maybe reducing the trocar diameter could be a little bit safer, is that what this is finding?
A. That reducing the trocar diameter may give you a slightly better result, yes.
Q. By better, safer, less morbidity, right?
A. Well, the quality of life is not a morbidity question. Quality of life is how patients are feeling and how much it's bothering them.
Q. I appreciate that.
The difference in diameter may result in a more limited dissection, right?
A. Correct.
Q. Which could be safer, right?
A. I wouldn't want to use "safer"

Page 301

'cause I don't think that one -- the larger needles or the smaller needles have -- one has been proven to be safer than the other. This is a hypothesis over here, but I'm not aware of any clinical data saying that the -- there were more -- one was safer than the other.
Q. Just the patients had better quality of life with the smaller needle; whether or not that was the cause, you don't know?
A. Correct. It's an hypothesis.
Q. And you don't discuss this article in your report.
Is there any reason for that?
A. I don't think this article is on the safety and efficacy of the TVT. It just shows us one component.
And like I said, there's much better data out there than this study, fortunately, to substantiate my claims in my report.
Q. And the TVT's a kit that's sold, right?

Page 302

A. Yeah, I guess you can call it a kit.
Q. Well, the TVT actually includes the trocars, right?
A. Well, the TVT included the trocar, I guess the T part in the TVT, that was reusable. You know, the handle part, the Mickey Mouse handle part.
Q. That would be TVT disposable. But I think TVT comes with the trocars, right?
MR. BENTLEY: Let me rephrase that.
Q. Ethicon provides the trocars for the TVT, right?
A. Yeah, but there was a reusable device that screwed on to the TVT-R.
Q. Right.
A. That you -- that was reusable. That wasn't in the kit.
Q. Who designs and manufactures those?
A. Ethicon, J&J.
But I'm just saying that wasn't

Page 303

part of the kit.
Q. The trocar design was made by Ethicon, right?
A. The trocar design was made by Ethicon. That particular part of it was a reusable part, so it wasn't in each and every kit.
Q. I think I understand, your opinion is that the TVT and TVT-Exact are safe because they're safer than some of the other procedures? Is that generally it?
A. I think they are -- are a safe procedure, yes.
Q. And we're having a difficulty defining numerically what safe is, and I think that it's a relative analysis; is that correct?
A. Right. I think everyone's going to decide what safe is and some patients may consider one in a hundred safe, one in a thousand safe, one in ten thousand safe. So it's a really hard number to, or hard word to explicitly design -- define.

Page 304

Q. And part of the way we've defined it today is safety, or your analysis of safety is based upon the relative safety of this device versus alternative procedures and devices, right?
A. Correct.
Q. Because there's no absolute a hundred percent safe?
A. No. Don't have surgery if you're looking for a hundred percent of anything.
Q. And we discussed that you are relying upon other people's systematic reviews and meta-analysis, right?
A. I'm relying on them as well as my clinical experience.
Q. Because we're not doing statistical analysis here. That's someone else's expertise, right?
A. When I reviewed a paper, I did not do a statistical analysis. I will try to review the statistics, but I'm not doing a breakdown of the analysis each time.

Page 305

Q. If you could please turn to page 52. At the top of the page you're discussing the Schimpf 2014 meta-analysis review of RCTs.
Do you see that?
A. Yes, I do.
Q. And that's what we discussed was -- on page 52 of your report you're talking the Schimpf meta-analysis.
Do you see that?
A. Yes, I do.
Q. And you note that the Schimpf meta-analysis which reflected RCTs with at least 12 month follow-up, that --
A. That's accurate.
Q. And is 12 month follow-up important to you to note that here?
A. Well, I don't think if you're -- looking at data today, you wouldn't want to look at any data less than 12 months, for what's available.
Q. Because most of the complications occur within the first 12 months, right?

Page 306

A. Yes. Many of the -- the majority of complications will usually occur in the first 12 months.
Q. So this meta-analysis limited their review to RCTs, which are randomized control trials, right?
A. Yes.
Q. They have at least 12 month follow-up, so they're going to hopefully capture the majority of the complications right?
A. Well, there was at least 12-month follow-up, so there's follow-up that's longer in there as well.
Q. Even better, right?
A. Correct.
Q. And you note that they found comparing midurethral slings to Burch there's no difference in objective or subjective cure, quality of life, or sexual function to outcomes.
Do you see that?
A. Yes, I do.
Q. And these authors, after

Page 307

reviewing RCTs with at least 12-month follow-up, found that there was really no difference.
Do you have some criticism or critique of their findings?
A. I do not have criticism. I have never once stated that a Burch is a bad procedure. A Burch has a good outcome. However, there's increased morbidity associated with the procedure as compared to midurethral slings.
Q. And here they're saying it has the same efficacy, right?
A. That's a good thing.
Q. Right?
A. (No verbal response.)
Q. And they note that with respect to complications, the slings have a lower rate of short-term complications compared to Burch, right?
A. Yes, they do.
Q. But you state: "Not surprisingly, the slings had a higher rate of long-term return to the operating room for retention

Page 308

or erosion and OAB symptoms."
Is that correct?
A. Yeah.
So, slings, whether it's a synthetic sling or a pubovaginal sling, have a higher risk of voiding dysfunction or obstruction, so that's why it's going to be a higher chance for those patients to go back to the operating room to release or cut the slings and there is no -- there's less risk of exposure or the incidence of exposure with a Burch procedure in lower than with the sling procedure. So it's not surprising that patients went to the back operating room for that.
Q. So, the Burch was as effective as the slings, right?
A. Yes.
Q. And slings had a higher rate of reoperation -- and the slings had a higher rate of reoperation as compared to the Burch, right?
A. That's not what I said. And if

Page 309

you read the next line: "However, their studies did not consider patients to return to the operating room for prolapse which occurs in 13.6 of patients who undergo a Burch procedure."
So, they didn't include in the study in their Burch patients the number of patients that had to go back to the operating room for a different reason. So, I'm just saying it's a little hard to make that comparison of reoperation rates.
Q. Are you saying that the development of prolapse is a complication of the Burch?
A. Prolapse can happen after the Burch procedure, yes. And that's a known common complication. And it's hypothesized that you're lifting up that anterior vaginal wall, there's more pressure going posteriorly, so causing an enterocele and prolapse.
Q. And can prolapse happen after a sling procedure?
A. It's a different type of

Page 310

procedure and we're not -- it can happen, but there's no causality that people have hypothesized that it's coming from the sling procedure.
Q. So --
A. They're different operations.
Q. I'm just trying to understand how you've incorporated this meta-analysis that use RCTs with 12-month follow-up that appears to have findings not supportive of your opinion. I'm trying to understand why you discounted that.
A. No, it's totally supportive of my opinion. I think you're misreading it.
I'm just saying that they didn't consider this component in their analysis of what they were comparing reoperation rates.
Q. So this found there was a higher reoperation rate with slings, right?
A. Yes, for these problems, for retention, erosion and OAB. And my understanding is they didn't include patients who had to go back to the

Page 311

operating room for prolapse that develops after a Burch procedure. That's all I'm saying.
Q. Is that your one criticism or critique of --
A. That's the one that I wrote. If we want to go through line-by-line for the article.
Q. Well, today is I've got to learn all of the bases for why you're discounting the study.
A. I'm not discounting it. All I'm saying is that is one thing they did not consider.
I wouldn't discount an entire study based on one thing.
Q. Help me explain why is this study supportive of your opinion then?
A. Well, it says a couple of things over here. That subjective cure outcomes of TVT versus pubovaginal vaginal slings after TVT. Retropubic slings had less blood -- retropubic slings had less blood loss, transfusions, wound infections,

Page 312

retention, OAB symptoms, shorter operating time and hospital stay.
I'll read on.
Q. No, hold on.
The fact that they had less blood loss, that's important to you?
A. Yes.
Q. The fact that they had a shorter operating time, that's important to you?
A. Yes, that's the benefit to the patient. Less blood loss, shorter operating time is a benefit to the patient.
Q. Less obstruction is important, right?
A. Correct.
Q. And less transfusions, right?
A. Correct.
Q. Those are all important indicators of -- to take into account when you're deciding whether or not to undergo a procedure, right?
A. Those are all components of morbidity.

Page 313

Q. And that was a comparison between TVT and pubovaginal slings, right?
A. Correct.
Q. And then comparing the midurethral slings to Burch, there was no objective or subjective cure, quality of life, or sexual function outcomes, right?
A. Correct, and I think that's an important statement.
Q. That it's the Burch and the TVT are essentially the same for efficacy and for those outcomes?
A. For those -- yes, for those outcomes.
Q. But retropubic slings had a higher rate of reoperation than Burch, right?
A. So, that's where my criticism comes in because we don't know the total reoperation rate for patients with Burches because they didn't include the patients who may have gone back to the operating room for prolapse.
Q. At the bottom of that page,

Page 314

Doctor, you note that "As a testament to safety and efficacy."

Do you see that paragraph?

A. Yes.

Q. You end that paragraph with: "The FDA is not requiring any further studies for the TVT sling to support its user safety."

Do you see that?

A. Correct.

Q. That's part of your explanation as a testament to the safety and efficacy?

A. Yeah, and if I remember correctly, what the FDA, don't point me, came out in their 2013 statement saying that there was a safety and efficacy to support the use of the full-length slings.

Q. I think I understand.

So, you say: "As a testament to the safety and efficacy," and you're discussing the TVT slings, right?

A. Correct.

Q. And one of the bases for your opinion that they're safe and effective is

Page 315

the FDA has not required further studies of the TVT sling for support -- to support its use or safety; is that correct?

A. Correct.

And we discussed the 522 studies which you asked me about prior.

MR. BENTLEY: Thank you, Doctor. That's all I have for right now.

THE WITNESS: Okay.

MR. BENTLEY: For those products.

THE WITNESS: I figured that much.

MR. BENTLEY: For the record, plaintiffs are moving to keep the deposition open pending review of the production materials that were produced prior to this deposition, it was that thumb drive with extensive materials on it that we haven't had a full opportunity to review. Should we find something that is important, we reserve our right to come back.

And it's our understanding

Page 316

there's also not a production of internal documents associated with Dr. Winkler that we still have not adequately necessarily reviewed. If anything else pops up, we reserve our right to come back.

MR. ROSENBLATT: Objection noted.

I would just like to say for the record the flash drive that we provided you is consistent with the materials obtained -- that you can find on the reliance list that was produced with his report.

Additionally, we are under no obligation to hand you on a platter every single produced document that references Dr. Winkler. You guys have access to those documents.

We have objected to your document requests, and we'll object to any deposition outside of today.

MR. BENTLEY: And just to clarify regarding the objections to

Page 317

the notice, there was a couple of RFPs where they were simply objected to and Ethicon did not state that it was producing any responsive documents. They were standing on the objections. And it's our contention that there's clearly relevant and responsive material that we need in preparation for this deposition that we may not have found, and if it's in the database, we would reserve our right.

Thank you.

MR. ROSENBLATT: Okay. We'll maintain our objections to that, but your objection is noted.

EXAMINATION BY
MR. ROSENBLATT:

Q. Dr. Winkler, thank you for being with us today.

My name is Paul Rosenblatt. I represent Ethicon Inc. and Johnson & Johnson.

Doctor, you recall being asked some questions about your CV?

Page 318

A. Yes, I do.
Q. That was marked as Exhibit 3.
Do you have that in front of you?
A. I will try get that.
Yes, I got it.
Q. On page 7 of your CV, you list some of the national and international courses or presentations that you've given.
Is that accurate?
A. That is accurate.
Q. And if it's possible that there may be a presentation or a professional education event, such as a cadaver lab or a preceptorship, that does not appear on this list, did you leave any out intentionally?
A. I didn't leave anything out intentionally. There's always a possibility that things were left out.
I had to go back in -- in 2011 to 2012 to try to figure out what courses I've taught where and when, and it was not

Page 319

an easy task to piece together.
Q. And you're certainly not trying to hide in your CV that you might have had some affiliations with industry in the past; is that fair?
A. I don't hide it. I think I mention it in my reports as well.
I believe that physicians need to work with industry as opposed to be enemies with industry.
Q. Doctor, if you turn to page 8, it says: "Mentoring of graduate students, residents, postdoctoral fellows and research."
Are these all of the graduate students, residents and fellows that you've taught throughout your career?
A. These are not at all all of them that I've taught. This is just a representation of residents that have decided to go into or attempt to go into female pelvic medicine who I had a closer relationship with as opposed to the hundreds and hundreds of residents that

Page 320

I've had exposure to throughout the year -- years.
Q. And on page 6 of your report, you list some additional teaching experience; is that fair?
A. Page 6 of my CV?
Q. Correct.
A. Yes. So, like I said, I tried to piecemeal together the early stuff that I did. Most of the early stuff that I did I tried -- you're going to see it's mostly local stuff. There's very little national or international stuff early on in my career. These were weekends that I took off, days that I took off from work, days that I was out of the office, days that I was away from my family. I did mostly grand rounds back then to try to help build my career and reputation and inform other people. But it was time away either from the office or the family.
Q. So if you received an honorarium from whoever was sponsoring the event, whether it was AMS or whoever, would that

Page 321

honorarium, or would you have been doing that speaking event for the purposes of getting that honorarium?
A. No, I wouldn't do it for the honorarium.
And back then, you know, things were different than they are today. So, today you would get your honorarium from the hospital that you were doing the grand rounds in. Back then, you may have gotten your honorarium from a company supporting it.
So, the -- the relationship that industry has with physicians and the relationship that industry has with hospitals has evolved over time.
Q. And for example, Doctor, if you turn to page 9 of your CV, you list some of the contracts, grants and sponsored research.
Do you see that?
A. Yes, I do.
Q. If you go through page 9, 10, 11, and 12, it lists various grants,

Page 322

predominantly sponsored by industry; is that fair?
A. That is fair.
And once again, I feel that we need to work with industry in order to meet our goal, improve patients' lives, improve safety and efficacy of products and to learn about products. It's expensive to run these studies, and institutions just don't have that kind of money sometimes.
Q. Just taking one, for example, on page 9 it says AMS and then $29,000, essentially.
Would that be money that's paid to you that goes into your pocket?
A. Absolutely not. None of this money goes into my pocket anywhere, actually. This money goes into a -- to a hospital fund, and we've been trying to restrict any money that we make on a grant to promote further research.
Q. So, if it were suggested at trial that you've been paid X-number of

Page 323

dollars from industry based on the calculation of pages 9 to 12, would that be accurate or inaccurate?
MR. BENTLEY: Objection; outside the scope; leading; compound.
A. This is inaccurate. Anything that was paid over here would have been paid to the hospital, and it will -- like for instance, if you go on the government Web site today, there is going to be a differentiation of money that I received to my pocket or money that I received for research dollars. And we didn't have that kind of strict rules back then, but this is all money that went to the hospital.
Q. Doctor, just looking at your list of publications, would it be fair to say that you have extensive experience publishing on treatments for stress urinary incontinence?
A. I have extensive experience on that. I've been reviewing journal articles for years. I've peer-reviewed

Page 324

journal articles for years. I've written journal articles with residents and fellows and myself throughout the last 20 years.
Q. What are some of the editorial positions that you've had that are listed on page 5 of your CV?
A. So, I've been a reviewer for the International Urogynecology Journal of Female Pelvic Medicine and Reconstructive Surgery. I've done journal reviews for the American Journal of Obstetrics and Gynecology, and I've also been -- I was an abstract reviewer, I guess for not this past one, but the previous AUGS meeting.
Q. Doctor, I want to show you your reliance list.
Do you see I think it's the fourth page from the end where it says "21 CFR 801.109(c) Device Labeling"?
A. Yes, I do.
Q. When you referenced the CFR that you relied upon, is that, in fact, the specific section that you relied upon?

Page 325

A. Yes, it is.
Q. Even though that is a specific section, have you in fact read the entire CFR related to, or at least skimmed the CFR related to device labeling?
A. Yes, I have.
THE WITNESS: Could we go off the record for a second?
(Discussion held off the record.)
BY MR. ROSENBLATT:
Q. Doctor, you were asked some questions about Burch and autologous fascial slings.
Do you recall those questions?
A. Yes, I do.
Q. If someone were to suggest that currently the Burch or the autologous fascial sling is the current gold standard treatment for uncomplicated stress urinary incontinence, would that be accurate?
A. It is not. I would disagree with that statement. It is not the current gold standard.
The current gold standard, as

Page 326

noted in multiple publications, as well as reviews, is the midurethral sling.
Q. I want to jump around a little out of order, Doctor.
A. No problem.
Q. You were asked some questions about frequency and severity of complications.
A. Yes.
Q. I believe you testified that you primarily rely upon the Level I medical literature for that information?
A. Yes, I do.
Q. Do you know if that's the general practice of surgeons in your field?
A. It is the general practice to rely on the highest quality data that's available.
MR. ROSENBLATT: Do you have the exhibit stickers?
(Exhibit Winkler 27, Unger article, was marked for identification, as of this date.)

Page 327

BY MR. ROSENBLATT:
Q. You were asked some questions about reoperation rates.
Do you recall those questions?
A. Yes, I do.
Q. I'm marking Exhibit 27.
MR. BENTLEY: Do you have a copy?
MR. ROSENBLATT: I've got them here (indicating).
MR. BENTLEY: Do you want to pull it out, or can I look at the binder or something? I don't have it necessarily.
MR. ROSENBLATT: Go off the record a second.
(Discussion held off the record.)
BY MR. ROSENBLATT:
Q. Doctor, I've just handed you Exhibit 27.
Is this a study that was referenced in your report?
A. Yes, it is.
Q. And it's by Unger titled

Page 328

"Indications and Risk Factors For Midurethral Sling Revision."
Do you see that?
A. Yes, I do.
Q. And they noted in the conclusion the rate of sling revision after midurethral sling placement was 2.7 percent?
A. I see that and I agree with that, correct.
Q. And this was based on over 3,000 women?
A. Who underwent the sling, yes.
Q. So, do you rely on literature such as the Unger study to get a better understanding as to what the overall expected and acceptable revision rates are for midurethral slings?
A. Yes, it's one of the studies that I would rely on.
(Exhibit Winkler 28, Welk article, was marked for identification, as of this date.)

Page 329

BY MR. ROSENBLATT:
Q. I'll hand you what I've marked as Exhibit 28 which is a study by Welk titled "Removal and Revision of Vaginal Mesh Use For the Treatment of Stress Urinary Incontinence."
Do you see that?
A. Yes, I do.
Q. Is this also a study that was referenced in your report?
A. Yes, it is.
Q. You'll see that they noted: "Complications were treated in 1,307 women at a rate of 2.2 percent."
A. Yes, I see that.
Q. And the 10-year cumulative incidence rate was 3.29.
A. I see that.
Q. And that the conclusion states: "10 years after SUI surgery, 1 of every 30 women may require a second procedure for mesh removal or revision."
Do you see that?
A. Yes, I do.

Page 330

Q. And that: "Patients of lower volume surgeons have a 37 percent increased likelihood of having a complication."
Do you see that?
A. I do see that.
This is what I based some of my experience with, the literature that is out there of the 1 in 30. However, I'm a higher-volume surgeon who does many of these procedures. So in my clinical experience and my follow-up, we've seen a slightly lower rate.
Q. What does that indicate to you as to whether or not the mesh of TVT or midurethral slings is defective based on there being a difference between high-volume versus low-volume surgeon?
MR. BENTLEY: Objection.
A. I don't think it's defective on the product at all. I think it's based on the decision process of who may be getting a sling. I think it may be based on the decision of what type of sling was placed,

Page 331

and on the tissue quality, most importantly, of some of these patients, as well as the dissection that's performed by these surgeons.
Q. You were asked a lot of questions about what you considered to be acceptable complication rates.
Do you see those?
A. Yes, I do.
Q. If a study showed a slightly higher rate based on the ones that you discussed, would you automatically consider that to be unacceptable?
A. Absolutely not. And once again, it always depends on what those complications are and what are we talking about. It all needs to be taken in context as opposed to just the number.
Q. So for example, are there different patient types that might be more prone to a complication, such as a smoker versus a non-smoker?
A. Yes, a smoker, somebody who may be on chronic steroids, or age sometimes

Page 332

comes into play, postmenopausal, older woman. All these things have to factor in when you're having a discussion with a patient of acceptable surgical risks.
Q. And so, if a patient had dyspareunia before a midurethral sling procedure and then had dyspareunia after a midurethral sling procedure, would that indicate that the sling is defective just because the patient continued to have dyspareunia?
A. Absolutely not. The patient had dyspareunia. And there's some data to support that patients who have chronic pain-type syndromes may have more complications than patients who do not, and that's something that we would discuss with patients as well.
Q. Doctor, I want to refer you to what I've marked as Exhibit 29.
(Exhibit Winkler 29, Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update, was marked for identification,

Page 333

as of this date.)
BY MR. ROSENBLATT:
Q. This is the AUA Guideline For the Surgical Management of Female Stress Urinary Incontinence: 2009 Update.
A. Yes.
Q. It shows that it's revised in 2012.
A. Yes.
Q. Doctor, if you look on the second to last page under "Slings synthetic at midurethra" in the middle column.
A. Yes.
Q. And you go down to "Subjective Complaints," what is listed for pain?
A. One percent.
Q. What is listed for sexual dysfunction?
A. Zero percent.
Q. What is listed for voiding dysfunction?
A. Two percent.
Q. And is that generally consistent

Page 334

with your understanding of the subjective complication rates of pain, sexual dysfunction and voiding dysfunction that were reported for synthetic midurethral slings in the clinical literature?
A. Yeah, that's my understanding. And acceptable is very subjective type of a question. That's why I have difficulty answering it.
Q. So, even though you were answering questions about specifically asking about acceptable, would it be more appropriate to consider those just kind of general rates that are more commonly seen in the literature?
A. Yes, I would agree with that.
Q. And are the complications that you notice in your practice generally consistent with the medical literature related to synthetic midurethral slings?
A. Yes, absolutely.
Q. And what is that based on?
A. So, that's based on my review of the literature and seeing patients back

Page 335

postoperatively, as well as reports from patients, seeing them in the long-term, long-term patients returning to my office for various reasons, as well as discussion with other referring physicians, and colleagues that would manage complications if this -- if a patient came back to another physician and then telling me. We speak all the time and sometimes I even ask have you seen any of my complications recently.
Q. And as I understand it, you may not have a formal spreadsheet that tracks all of your complications over the past two decades.
But how would you say you're able to characterize your general understanding of complication rates and whether or not they're higher or lower than what you would expect?
A. I don't see a significant number of women coming back in complaining of pain and/or dyspareunia. Majority of the women just say "I wish I would have done

Page 336

this earlier, this procedure, and not have waited that long."
Q. And do you track your complications in more of an informal basis?
A. So, we track complications formally. However, we don't write down our complications all the time. We have biweekly and/or monthly internal morbidity and mortality meetings. Thank God we don't have too many people who died from our procedures, or it's pretty rare. But we have morbidity where we talk about our complications. We talk about the complications that have come into the office and/or have gone to the operating room. So we do that on a formal and informal basis. And if we have a serious complication, that may get presented in hospital M&M rounds. And M&M rounds are protected by confidentiality.
Q. And going back to the AUA guideline that we are looking at.
The page showing suspensions in

Page 337

the middle column Burch suspension.
A. Yes.
Q. What does it report for pain?
A. So, pain was 6 percent, sexual dysfunction is 3 percent, and voiding dysfunction is 10 percent.
Once again, difficult ways to get pinned down of what's an acceptable rate for anything.
Q. And so, although those rates for the Burch procedure with respect to pain, sexual dysfunction, and voiding dysfunction are higher than the reports seen and the reports -- or the complication rates that you discussed earlier, that doesn't necessarily automatically make those rates for that procedure unacceptable; is that fair?
A. That's fair. It's just recording the rates, and nobody's making a determination here of what's acceptable and unacceptable.
Q. And would it be fair to say that rather than saying acceptable or

Page 338

unacceptable, you would always perform a risk-benefit analysis?
A. Right. So, with each individual patient, you need to perform the risk-benefit analysis of what's going to be a more acceptable procedure risk-wise for them.
Q. And so, although I take it you wouldn't necessarily consider the Burch procedure to be an unsafe procedure, based on your testimony, it sounds like after performing a risk-benefit analysis with your patients, they seldom select to proceed with the Burch procedure; is that fair?
A. That is fair. And the clinical data reports lower morbidity with midurethral slings.
Q. Looking under "Slings" where it states: "Autologous fascia without bone anchors."
Do you see that?
A. Yes, I do.
Q. And if you go down to the

Page 339

subjective complications, what are the complications reported for the autologous fascial sling, based on the AUA's analysis?
A. Ten percent for pain, 8 percent for sexual dysfunction.
Q. And then there's an asterisk for voiding dysfunction where it states: "Only case reports of this complication exist and data are insufficient to estimate the frequency."
Do you see that?
A. Yes, I do.
Q. And so, based on the AUA's analysis of the literature for synthetic midurethral slings, autologous fascial slings, and Burch, would it be fair to say that pain, sexual dysfunction, voiding dysfunction are typically lower with synthetic midurethral slings?
MR. BENTLEY: Objection; vague; leading; compound.
A. Yes, they're lower with the midurethral sling.

Page 340

Q. Is that consistent with your clinical practice?
A. Yes, it is.
(Exhibit Winkler 30, Schimpf article, was marked for identification, as of this date.)
BY MR. ROSENBLATT:
Q. I'm going to hand you what I've marked as Exhibit 30, which is the Schimpf meta-analysis.
Doctor, are you familiar with what's been marked as Exhibit 30?
A. Yes, I am.
Q. And is this the systematic review performed by the Society of Gynecologic Surgeons?
A. Yes, it is, by a committee from them.
Q. Doctor, if you turn to table 3 reporting adverse events.
What is the rate reported of dyspareunia for retropubic midurethral slings?
A. It's 0 percent with a 95 percent

Page 341

confidence interval of .01 percent to 1.64 percent.
Q. And for exposure, what is the percentage listed for retropubic slings?
A. Exposure retropubic slings is 1.4 percent.
Q. And so, Doctor, although there may be studies that show a higher rate or a lower rate, do you rely on Level I evidence such as systematic reviews like the Schimpf review, in order to support your opinions about generally accepted and expected complication rates?
A. Yes, I rely on the literature, as well as my clinical experience.
Q. Are the complications that you see in your clinical experience generally consistent with the Level I literature?
A. Yeah, the complications that I see are expected with the Level I literature.
(Exhibit Winkler 31, Ford Cochrane review, was marked for identification, as of this date.)

Page 342

BY MR. ROSENBLATT:
Q. Handing you what I've marked as Exhibit 31, which is the Ford Cochrane review.
Is this a review that you referenced in your report?
A. Yes.
Q. Doctor, this systematic review is based on 81 randomized control trials that evaluated over 12,000 women?
A. Yes, that's accurate.
Q. You recall being asked some questions about SPARC versus the TVT?
A. Yes, I do.
Q. And the SPARC would be a top-down sling?
A. Yes, it is.
Q. And TVT would be -- the TVT and TVT-Exact that we're talking about today would be a bottom-up approach?
A. Yes, it is.
Q. Do you see where it states: "A retropubic bottom-to-top route was more effective than top-to-bottom route for

Page 343

subjective cure. It incurred significantly less voiding dysfunction and led to fewer bladder perforations and vaginal tape erosions."
Do you see that?
A. I see that and that's what I hold by today.
Q. Would a systematic review, such as the Ford Cochrane review, look at more patients and more data than the 2011 article that looked at 113 patients?
A. Definitely. That is a much -- the Cochrane review is a much higher level of evidence than my paper.
Q. And when you're practicing evidence-based medicine, would you rely on the results of Cochrane review such as this Ford 2015 Cochrane review as opposed to one study?
A. A hundred percent I would rely on the Cochran review over the one study, and that's how I practice today.
Q. Doctor, the authors' conclusions for the Ford Cochran review states:

Page 344

"Midurethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence, SUI, in women and have a good safety profile."
Do you see that?
A. Yes, I do.
Q. And is that consistent or inconsistent with your opinions in this case?
A. That's consistent with my opinions.
Q. Doctor, looking on page 10 of the Ford review, do you see where they describe synthetic meshes as being type 1, type 2, type 3, or type 4?
A. Yes, I do.
Q. And they describe type 1 as being macroporous and monofilament?
A. Correct.
Q. What is your understanding as to what type of mesh Prolene TVT is?
A. It's a macroporous monofilament mesh. It's a type 1.

Page 345

Q. That's a type 1 classification?
A. Yes, it is.
Q. And this is from 2015?
A. Correct. Most recent Cochrane review on slings.
Q. And it states a little further down: "Type 1 mesh has the highest biocompatibility with the least propensity for infection."
Is that consistent or inconsistent with your opinion?
A. That's consistent with my opinion.
Q. Doctor, if you could pull out Exhibit 26, which is the study we were just comparing there.
A. Yes, I got it.
Q. This is a study where you were a co-author comparing Ethicon's TVT to AMS's SPARC?
A. Correct.
Q. And on the last page, the last paragraph states: "In conclusion, both the suprapubic and the transvaginal

Page 346

procedures."
Which would be the TVT.
A. Correct.
Q. (Continuing) "were associated with a significant improvement in quality of life as measured by the UDI-6."
Do you see that?
A. That is correct.
Q. So they're not saying that there was a worsening of quality of life after TVT, but just that in this study with these patients, the SPARC had a higher increase in quality of life compared to the TVT.
Is that accurate?
A. That's accurate.
Q. And under the "Discussion," the first paragraph it says: "The surgical management of stress incontinence has advanced from the Burch colposuspension and pubovaginal sling techniques to the newer midurethral approaches designed to achieve at least similar efficacy while reducing morbidity in postoperative

Page 347

recovery. Midurethral sling procedures are the most commonly performed anti-incontinence procedures and are safe and efficacious."
Do you see that?
A. Yes, I do.
Q. And is that consistent or inconsistent with your opinions?
A. Entirely consistent.
Q. Although the authors on this paper were suggesting that there might be differences in the quality of life based on the needle size, you see at the bottom of the discussion here where it states: "It is unclear why a significantly greater improvement in UDI-6 was seen in the suprapubic treatment group"?
A. Yes. We couldn't come up with a clear explanation.
Q. So, would you use this study to definitively say that the needle size definitively was the cause for the increase or decrease in quality of life?
A. Absolutely not. We could not

Page 348

figure out causality.
Q. In fact, in the conclusion it states: "Complication rates in new onset urinary urge incontinence were low in both groups"?
A. Yes. And then we even write that the study design provided only Level III evidence.
Q. Which would be lower than, say, a systematic review, right?
A. Exactly. Lower than Level I, for sure.
Q. And if you turn to the results page in the paragraph that starts: "Concomitant surgery was performed in 75.7 percent of patients who underwent the suprapubic sling procedure." Which would be the TVT. And in 90 percent of the -- or, the SPARC.
A. Correct.
Q. And in 90.7 percent of those who underwent the transvaginal procedure.
A. Correct. So, those are all risk factors for having possibly decreased

Page 349

quality-of-life rates afterwards.
Q. And if you look at table 1, it appears that the TVT group had more concurrent prolapse surgeries, more vaginal hysterectomies, more anterior repairs, more posterior repairs, more paravaginal repairs than the SPARC group.
Is that accurate?
A. That is correct.
Q. Okay. You can put that aside.
Doctor, looking at your report on page 26.
A. Yes.
Q. You were asked some questions about mesh characteristics, and I think you referred to the Moalli study.
A. Yes.
Q. Is this a chart from the Moalli study?
A. Yes, it is.
Q. Under "Mesh Type" it lists six different manufacturers.
A. Yes, it does.
Q. And Gynecare would be Ethicon?

Page 350

A. Yes.
Q. And out of all of the manufacturers, which mesh had the largest pore size as described in the chart on Moalli?
A. The largest pore size is the Ethicon Gynecare mesh.
Q. And that shows 1,379 microns?
A. Correct.
Q. Compared to Boston Scientific's Advantage mesh which was 1,182 microns?
A. Correct.
Q. But it looks like the fiber size with respect to diameter was the same for TVT versus Advantage mesh?
A. That's correct.
Q. And the weight is similar at 100 grams per meter squared for TVT versus the Advantage mesh?
A. Yes, that's true.
Q. And the Advantage mesh made by Boston Scientific has a laser or a heat-sealed portion under the midurethra?
A. That is correct.

Page 351

Q. And then the rest of the sling would be what we call a tanged or mechanically-cut?
A. Correct.
Q. Have you ever noticed any particle loss with the tanged or mechanically-cut portion of the Advantage mesh?
A. I have not noticed any.
Q. Have you noticed any complications or any problems with particle loss roping, fraying, curling, degradation or cytotoxicity related to the TVT mesh?
A. No, I have not.
Q. And regardless of whether the TVT at the time you were using it was TVT mechanically-cut or TVT laser-cut?
A. Regardless, they were both the same.
Q. And although you don't have a spreadsheet tracking the complications, throughout your career, have you noticed a difference in the complications between

Page 352

mechanically-cut versus laser-cut?
A. I have not noticed an increase or decrease in the complications or patients returning for complications based on either.
Q. And is there any reliable peer-reviewed clinical literature that has confirmed that there is a difference?
A. There is no reliable literature that I'm aware of that has confirmed that.
Q. And so, although there may be studies where authors suggest, such as in your paper where you're describing what might be the cause for something, that doesn't definitively establish causation, correct?
A. No, it does not, correct.
Q. I believe you testified that biologic slings don't have substantial efficacy as reported by clinical literature?
A. That's true.
Q. And so, would it be accurate or inaccurate to refer to biologic slings for

Page 353

primary incontinence as the gold standard?
A. They are not the gold standard. It would be inaccurate to refer to biologic slings as the gold standard.
Q. And most of the long-term data that exists for TVT, is that on the laser-cut or the mechanically-cut?
A. The long-term data is mostly on the mechanically-cut.
Q. You talked about having to perform release procedures after midurethral slings.
You recall those questions?
A. Yes, I do.
Q. Have you had to perform similar release procedures for autologous fascial slings or biologic slings?
A. Well, for the autologous fascial slings, the procedure for voiding dysfunction actually is a little more difficult. Usually instead of just incising the sling, you would do a full urethrolysis where you would go in and either cut the sling on both sides and go

Page 354

behind the urethra and dissect behind to take down some of the scarring that occurs with the pubovaginal sling.

Q. Doctor, jumping around a little bit, we were talking about levels of evidence and the Oxford levels.

Do you recall that?

A. Yes, I do.

Q. How does the quality of evidence on Burch and autologous fascial slings and biologic slings compare to the quality and volume of evidence on TVT and synthetic midurethral slings?

A. The quality and volume of evidence on TVT slings is significantly more on those than on Burch and pubovaginal slings and better quality and more evidence.

Q. When you were asked questions about Dr. Rosenzweig's opinions on mechanically-cut versus laser-cut, did you, in fact, go through and review Dr. Rosenzweig's expert report as well as the materials that he cited in the body of his

Page 355

report?

A. Yes, I did.

Q. And did any of those materials change your opinions?

A. No, they did not.

Q. You were asked about your presentation that showed a image of mesh being similar to reinforced concrete.

Do you recall that?

A. Yes, I do.

Q. Were you in any way trying to suggest that mesh is difficult to remove like rebar might be difficult to remove from concrete?

A. Absolutely not. It was just a philosophical type of explanation of what the mesh does.

Q. Was it more so just to describe the scaffolding and how the mesh works by providing support?

A. Yes, it was.

Q. Doctor, do you recall reviewing a rabbit study where Ethicon looked for mesh particles within the muscle?

Page 356

A. Yes, I do.

Q. In this column, what did they show as far as whether there were any mesh particles in the muscle?

A. There was no evidence of such.

MR. BENTLEY: Is it marked?

MR. ROSENBLATT: No. Do you want me to mark it?

MR. BENTLEY: I don't know. I just thought that --

MR. ROSENBLATT: I was just going to try to wrap up.

MR. BENTLEY: That's fine.

BY MR. ROSENBLATT:

Q. Doctor, you also brought with you a photograph.

A. This one (indicating)?

Q. Exhibit 25.

Why did you bring this photograph with you?

A. I wanted to show that roping and curling, even with erosions, does not occur. Usually it would, and the mesh is not shrinking and contracting. It's just

Page 357

being exposed out.

Q. And how would you describe the pore size of that TVT mesh?

A. Without a ruler, it looks pretty similar to how we put it in and above a millimeter.

Q. Does it look to be an open pore or a collapsed pore?

A. It's an open pore.

Q. Doctor, I believe you had testified a little bit about your experience with companies and industry.

Have you consulted with industry on safety of products and devices with respect to warnings, as well as design?

A. Yes, I have.

Q. And did you describe some of that experience throughout your deposition?

A. Yes, I have.

Q. Doctor, on page 37 -- I'm sorry, 38 of your report.

A. Okay.

Q. If you could turn there for me.

Page 358

The last paragraph you reference the AUGS urogynecology resident objectives.
Do you see that?
A. Yes.
Q. On the next page, the last sentence says: "The resident should be able to discuss risk, benefits, expected outcomes of non-surgical and surgical management of SUI."
Do you see that?
A. Yes, I do.
Q. You also identify the 2012 ABOG and ABU guidelines for earning an FPMRS?
A. Yes, I do.
Q. You go through in your report and identify some other documents that you're relying upon.
Are these just some of the documents that you're relying on to demonstrate what surgeons are expected to know?
A. Yeah, these are some of them.
Q. And so although you may not know

Page 359

exactly what every surgeon does or does not know, what is your opinion as to what surgeons should be expected to know about commonly known complications?
MR. BENTLEY: Objection.
A. Surgeons should be expected to know that based on their education, training, and reading of the literature, as well as maintenance of certification.
Q. Doctor, you testified that you're currently performing for your retropubic slings either Boston Scientific's Advantage mesh or the TVT-Exact.
A. Correct.
Q. Does the fact that you're not currently performing TVT mechanically-cut, is that based on any concerns that you have about the safety of TVT mechanically-cut?
MR. BENTLEY: Objection.
A. That's not based on any of the concerns. I have not seen a noticeable difference, nor is it reported clinically,

Page 360

of mechanically-cut versus laser-cut.
Q. And are all of the opinions that you've offered in your report, as well as here today, held to a reasonable degree of medical certainty?
A. Yes, they are.
MR. ROSENBLATT: No further questions.
FURTHER EXAMINATION BY MR. BENTLEY:
Q. Doctor, you testified that you wouldn't want to hide your affiliation or work with industry.
Do you remember that?
A. Yes.
Q. And you --
A. And I -- any time if I was required to disclose it, I did disclose it.
Q. In your report for this matter discussing the TVT and TVT-Exact, you note that you've worked for industry, right?
A. Yes.
Q. And why in your report do you

Page 361

not discuss that you've worked for Ethicon who's hired you to act as their expert in this case?
A. I don't put any of my expert witness information on my CV. I've done expert witness for medical malpractice, and I haven't put that on my CV.
Q. I'm talking about in your TVT and TVT-Exact report in which you disclose that you've worked for industry, right?
A. Yes.
Q. Okay. In your TVT and TVT-Exact report, is there any reason why you don't disclose that you've previously consulted and taught for Ethicon?
A. Did I write in my report that I specifically consulted for other companies? I don't think I did that. Why should I single one out.
Q. That wasn't my question.
Is there any reason why you didn't disclose in your report regarding TVT and TVT-Exact that you have specifically consulted for the

Page 362

manufacturers of these products?
A. There's no reason for that.
And it explicitly says in my report my fee schedule, and everyone in the jury or everyone will know exactly what I'm getting paid and how much I'm getting paid, and you have my invoices.
Q. If you were going to update your report, would you want to include any information about your previous consulting work with Ethicon?
A. I don't -- if -- I don't think that's required in the report. It's not -- it's disclosable and I'm telling you about it, but the report is really based on my review of the literature and my clinical experience today, not money that I received 15 years ago.
Q. When you were updating your resume around 2013 and you went and added a lot of the earlier 2000 AMS and Boston Scientific work, how did you remember to add that information in 2013?
A. Some of that stuff I had written

Page 363

with some papers and whatnot.
There was a time when me and my partner were combining our stuff that we did. There was a time that I was recording it and there was a time that he was recording it, or we had somebody else recording it, and some of that stuff I had written, but I didn't have all of it recorded. And then we stopped doing that as well.
Q. When did you first --
A. But I don't -- I mean, if I -- I don't recall, and it's possible I may have taught one, but I did not do any significant cadaver labs for Gynecare. I may have done one or two, I don't recall those, and those are what I put on my CV because those are teaching labs to -- that's teaching experience to multiple doctors.
Q. I think you're testifying that you have notes or you had notes in 2013 documenting a lot of the work you did in the early 2000s for AMS and Boston

Page 364

Scientific?
A. No, I don't have notes. I have just some labs that I went to and what was there. I don't have specific -- I have little tidbits here and there, and I have some of that, but I don't have it all, unfortunately.
Q. When you did the updates in 2013, that was just based off your memory, your recollection of what happened in the early 2000s?
A. It was based on my -- most of it was based on my recollection, yes.
Q. And you didn't recall that you had also done work for Ethicon?
A. No, I never denied that I was a preceptor for Ethicon. I don't recall doing any kind of labs for Ethicon.
Q. We looked at your study that was comparing SPARC to TVT, and I believe your explanation for not including that in your report was because it was Level III evidence.
Was that correct?

Page 365

A. You're talking about my report for --
Q. Your report that found that AMS product had a higher quality of life compared to the TVT Retropubic.
Remember that?
A. Yeah, I do.
First of all, I thought it was low-quality evidence, and there was nothing in that report that would show that either of the slings, which are very, very similar, was defective.
Q. And my question is did you include other Level III evidence in your TVT report?
A. I may have. However, I -- once again, if Level I data is available, I would try to include the Level I data. If there's no Level I data, I would go to 2 and then I would go to 3.
Q. I believe you testified that Prolene is a type 1 macroporous mesh, right?
A. I think I testified that TVT is

Page 366

a type 1 macroporous mesh, not Prolene.
Q. You understand that TVT is made from Ethicon's Prolene mesh, do you?
A. I understand that. But you can weave Prolene differently. You can make the pores smaller.
So that's why I want to be specific we're talking about that.
Q. It's confusing.
Prolene is the name of a suture, right?
A. Yes.
Q. And then the mesh construction that's in the TVT product that Ulmsten originally used and it's still --
A. It's called the Prolene mesh, I agree with you.
Q. And that Prolene mesh is considered type 1 macroporous per the Amid classifications?
A. If we're talking about the Prolene mesh.
Q. Right.
A. Yes.

Page 367

Q. Do you understand that that mesh was created for application in hernia repair?
A. Yes, I do.
Q. And do you understand Ethicon subsequently made newer meshes, such as Prolene Soft?
A. Yes, I'm aware of that.
Q. And subsequently Ethicon's made ULTRAPRO also, which is I think a softer mesh with a partially absorbable component?
A. Correct.
Q. And those meshes are actually lighter weight than the original Prolene mesh that's used in TVT?
A. That's correct.
Q. And Ethicon never updated the TVT mesh with those newer meshes, correct?
A. Well, from the data, I think they actually looked at using ULTRAPRO in their mesh and they submitted to the FDA and that was denied by the FDA.
And if I remember correctly,

Page 368

there was some problems removing the sheathe using the ULTRAPRO mesh. I think in the sterilization process, the plastic got stuck to the mesh. So I think Ethicon was trying to see if there were alternatives to their mesh there.
There's also a study noted in my report comparing the TVT -- comparing a heavier-weight mesh, which you pointed out to me, to a lighter-weight mesh, and the lighter-weight mesh didn't perform as well as the heavier-weight mesh.
Q. And by "perform," you're talking about its ability to effectively treat incontinence; is that correct?
A. So, I'm referencing the Prien-Larsen study published a prospective study comparing the 100 gram meters squared with low stiffness and rough edges to lighter weight 60 grams per meters squared, and in 12 months there was a significant difference in objective cure rates favoring the heavier-weight mesh 86 versus 96 percent.

Page 369

Q. Right. And I'm just trying to see do you understand that the purpose of going to a lighter-weight mesh is to reduce the histological response after implantation?
A. I understand that's the purpose, but you need to maintain the efficacy as well still.
Q. Do you have an opinion of whether Prolene Soft has a less inflammation response as compared to Prolene original that's in TVT?
MR. ROSENBLATT: Object to form.
A. The Prolene Soft fiber is a smaller fiber than the fiber used in the TVT mesh. There has -- and so that may result in a reduced chronic inflammatory reaction, but once again clinically, we don't see any clinical evidence from this chronic inflammatory reaction with the heavier-weight mesh.
Q. Doctor, you mentioned a couple of avenues by which physicians should know about different complications, and I think

Page 370

you talked about the literature and their training.

Do you remember that?

A. Yes, I do.

Q. And do you understand that one of the purposes of the IFU is to provide another avenue of information for physicians?

A. Yes, the IFU can provide another avenue.

Q. It's actually written for physicians, right?

A. Correct, it's written for the physicians.

Q. Are you still working as a consultant for Ethicon regarding product design or --

A. No, only for the expert work.

Q. When did your consulting, your non-litigation consulting work end with Ethicon?

A. So, I don't remember exactly. I don't have the contracts anymore, anything like that.

Page 371

Somewhere probably in the mid-2000s, '6, '7 -- probably '7, '8, somewhere around there.

Q. Definitely not after 2010?

A. I don't think so.

Like I said, I don't have the contracts, so I don't know.

Q. Do you have the ability to find out that information if you wanted to know it?

A. I don't think I have the ability.

You have the ability though.

Q. Have you asked Ethicon to provide you with that information so you can know when you were consulting for them?

A. I didn't ask them to specifically provide that because I know that I consulted for them and did preceptorships for them and went to an advisory board for that which I was actually shown that I was at for Gynemesh PS, which I'm sure will come out later.

Page 372

Q. Would you like to have a complete record of your work for Ethicon now that it's refreshed your memory that you worked for them?

A. I mean, to me it's past history. So, you can give it to me. I don't think it's going to change any of my opinions today. I'm going to go with what the data supports today.

I do expect to be paid for my time away from my family and away from leisure time watching T.V. And, you know, thing are expensive. That's just -- got to pay for the kids.

Q. When you testify before a jury, would you like to be able to provide a full and accurate description of your previous consulting work with Ethicon so the jury can know that?

A. I don't have a problem giving that information to them.

Q. So you'd want to know that?

A. I didn't say that. I said I wouldn't have a problem giving them that information.

Page 373

MR. BENTLEY: Thank you, Doctor.

MR. ROSENBLATT: Greg, if you want to mark his training history and go through that with him.

MR. BENTLEY: I mean, it was in my document request. I don't know if it was in the stuff that I was produced. I tried to find it. And that's part of the problem is there's a lot of work and there's a lot of gaps in it and I just don't know.

THE WITNESS: Do you want to go off the record for a second?

MR. BENTLEY: That actually needs to be on the record.

I'm good. I have no further questions.

THE WITNESS: Okay.

MR. ROSENBLATT: Just briefly.

FURTHER EXAMINATION BY MR. ROSENBLATT:

Q. Doctor, what was the purpose

of --
MR. ROSENBLATT: Strike that.
Q. Doctor, what was your understanding of the purpose as to why you were teaching various professional education courses and preceptorships for various companies, including Gynecare, Ethicon?
A. Okay. So, there were a couple of reasons.
First of all, I believe that we need to continue furthering our physicians and making sure that they are doing procedures safely. I think you want a high-volume surgeon teaching these procedures to others that may have not had as much experience with them. So I believe in the continuing medical education.
It is very hard for an attending doctor to learn new procedures that are out there. They need to -- there are resources, there's money that needs to be spent, there's time away from the

practice, and I wanted to be that resource.
Specifically, also, if there were people locally wanting to learn this procedure, I wanted people to come to my OR and for me to meet these people learning this procedure so we can develop relationships and referral patterns as well. There was benefit to me as well and getting a reputation out there as being a leading expert also when I taught these procedures. If they had a tough patient that they would not want to operate on, I welcomed the referral.
MR. BENTLEY: I'm sorry. I was going to lodge an objection to the extent it called for speculation.
And I'm going to object to the response to the extent it exceeded the question as non-responsive.
MR. ROSENBLATT: Okay.
BY MR. ROSENBLATT:
Q. Doctor, do you believe that your previous consulting experience in any way

biases your opinions that you've offered in your report?
A. No, I do not.
MR. ROSENBLATT: No further questions.
MR. BENTLEY: Thank you, Doctor.
(Exhibit Winkler 32, Ethicon Inc. Johnson & Johnson report dated March 3, 2003, was marked for identification, as of this date.)
(Deposition adjourned at 3:55 p.m.)

A C K N O W L E D G M E N T

STATE OF)
:ss
COUNTY OF)

I, HARVEY A. WINKLER, M.D., hereby certify that I have read the transcript of my testimony taken under oath in my deposition of March 12, 2017; that the transcript is a true and complete record of my testimony, and that the answers on the record as given by me are true and correct.

_____
HARVEY WINKLER, M.D.

Signed and subscribed to before me this _____ day of _____, 2017.

_____
Notary Public, State of

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C E R T I F I C A T E

STATE OF NEW YORK
COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:

THAT HARVEY A. WINKLER, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 15th day of March, 2017.

MARIE FOLEY, RMR, CRR

LAWYER'S NOTES

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